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Presidential Documents

Title 3—

The President

Proclamation 8993 of June 7, 2013

Flag Day and National Flag Week, 2013

By the President of the United States of America

A Proclamation

Each June, our Nation lifts its sights to the flag that has watched over us since the days of our founding. In those broad stripes and bright stars, we see the arc of the American story—from a handful of colonies to 50 States, united and free.

When proud patriots took up the fight for independence, they came together under a standard that showed their common cause. When the wounds of civil war were still fresh and our country walked the long road to reconstruction, our people found hope in a banner that testified to the strength of our Union. Wherever our American journey has taken us, whether on that unending path to the mountaintop or high above into the reaches of space, Old Glory has followed, reminding us of the rights and responsibilities we share as citizens.

This week, we celebrate that legacy, and we honor the brave men and women who have secured it through centuries of service at home and abroad. Let us raise our flags high, from small-town storefronts to duty stations stretched around the globe, and let us look to them once more as we press on in the march toward a more perfect Union.

To commemorate the adoption of our flag, the Congress, by joint resolution approved August 3, 1949, as amended (63 Stat. 492), designated June 14 of each year as ''Flag Day'' and requested that the President issue an annual proclamation calling for its observance and for the display of the flag of the United States on all Federal Government buildings. The Congress also requested, by joint resolution approved June 9, 1966, as amended (80 Stat. 194), that the President annually issue a proclamation designating the week in which June 14 occurs as ''National Flag Week'' and call upon citizens of the United States to display the flag during that week.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim June 14, 2013, as Flag Day and the week beginning June 9, 2013, as National Flag Week. I direct the appropriate officials to display the flag on all Federal Government buildings during that week, and I urge all Americans to observe Flag Day and National Flag Week by displaying the flag. I also call upon the people of the United States to observe with pride and all due ceremony those days from Flag Day through Independence Day, also set aside by the Congress (89 Stat. 211), as a time to honor America, to celebrate our heritage in public gatherings and activities, and to publicly recite the Pledge of Allegiance to the Flag of the United States of America.

IN WITNESS WHEREOF, I have hereunto set my hand this seventh day of June, in the year of our Lord two thousand thirteen, and of the Independence of the United States of America the two hundred and thirty-seventh.

[FR Doc. 2013–14045
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Rules and Regulations

Federal Register
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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

8 CFR Part 235

[Docket No. USCBP–2012–0030; CBP Dec. No. 13–09]

RIN 1651–AA95

Extension of Border Zone in the State of New Mexico

AGENCY: U.S. Customs and Border Protection, DHS.

ACTION: Final rule.

SUMMARY: This final rule amends Department of Homeland Security (DHS) regulations to extend the distance that certain nonimmigrant Mexican nationals presenting a Border Crossing Card, or other proper immigration documentation, may travel in New Mexico without obtaining a U.S. Customs and Border Protection (CBP) Form I–94 (Form I–94), Arrival/Departure Record. This change is intended to promote commerce and tourism in southern New Mexico while still ensuring that sufficient safeguards are in place to prevent illegal entry to the United States.

DATES: This rule is effective July 12, 2013.

FOR FURTHER INFORMATION CONTACT: Colleen Manaher, CBP Office of Field Operations, telephone (202) 344–3003, email: *colleen.m.manaher@cbp.dhs.gov.*

SUPPLEMENTARY INFORMATION:

Executive Summary

Under current DHS regulations, certain nonimmigrant Mexican nationals presenting a Border Crossing Card (BCC), or other proper immigration documentation, are not required to obtain a Form I–94 if they remain within 25 miles of the U.S.-Mexico border (75 miles in Arizona).[1] This region is known as the ''border zone'' and includes portions of Arizona, California, New Mexico, and Texas. The majority of Mexican nationals who are exempt from the Form I–94 requirement possess and apply for admission to the United States with a BCC. The BCC is one of the most secure travel documents used at the border and allows for faster processing at both the port of entry and interior immigration checkpoints. The currently issued BCC is a laminated, credit card style document with many security features, a ten year validity period and vicinity-read Radio Frequency Identification (RFID) technology and a machine-readable zone. Using these features, CBP is able to electronically authenticate the BCC against the Department of State (DOS) issuance records.

Although the border zone, established in 1953, was intended to promote the economic stability of the border region by allowing for freer flow of travel for Mexican visitors with secure documents, New Mexico has no metropolitan areas and few tourist attractions within 25 miles of the border and thus benefits very little from the current 25-mile border zone. In order to facilitate commerce, trade, and tourism in southern New Mexico, while still ensuring that sufficient safeguards are in place to prevent illegal entry to the United States, on August 9, 2012, CBP published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** (77 FR 47558), proposing to extend the distance certain Mexican nationals admitted to the United States as nonimmigrant visitors may travel in New Mexico without obtaining a Form I–94 from 25 miles to 55 miles from the U.S.-Mexico border. The NPRM also solicited public comments.

All but two of the 40 comments received were very supportive of the proposal. Those commenters supporting the proposed extension include local and state law enforcement officials, elected officials of the region, as well as individual citizens and other stakeholders in the business and academic communities. Many commenters stated that the expanded border zone will maintain security of the border while increasing economic activity in New Mexico's border region and providing a boost to this relatively impoverished region. The two commenters who oppose the proposed expansion cited security concerns. CBP is of the view that the expanded border zone will facilitate commerce, trade, and tourism in southern New Mexico, while still ensuring that sufficient safeguards are in place to prevent illegal entry to the United States. In addition to promoting the economy in this area and facilitating legitimate travel, the extension will increase CBP's administrative efficiency by reducing unnecessary paperwork burdens associated with the I–94 process and allowing CBP to focus resources on security enhancing activities to the greatest extent possible.

This rule will not impose any new costs on the public or on the United States government. Further, this rule is expected to reduce costs to Mexican visitors to the United States, improve security, and benefit commerce in a relatively impoverished region. The majority of comments that CBP received supported this conclusion.

Therefore, after consideration of the comments, CBP is adopting as final the proposed amendments to 8 CFR 235.1(h).

Background

Under § 235.1(h)(1) of the DHS regulations (8 CFR 235.1(h)(1)), each arriving nonimmigrant who is admitted to the United States is issued a Form I–94, Arrival/Departure Record, as evidence of the terms of admission, subject to specified exemptions. This form is not required for a Mexican national admitted as a nonimmigrant visitor with certain documentation if he or she remains within 25 miles of the U.S.-Mexico border (75 miles within Arizona), for no more than either 30 days or 72 hours, depending upon the type of travel document the nonimmigrant visitor possesses. The area bounded by these limits is referred to in this document as the ''border zone.''

To be admitted to the border zone without a Form I–94, a Mexican national must be in possession of a

[1] The I–94 requirement and exceptions can be found at 8 CFR 235.1(h). On March 27, 2013, DHS published an Interim Final Rule in the **Federal Register** (78 FR 18457) entitled ''Definition of Form I–94 to Include Electronic Format.'' The rule makes various amendments to 8 CFR to enable DHS to automate the Form I–94 at air and sea ports of entry.

BCC,[2] or a passport and valid visa, or for a Mexican national who is a member of the Texas Band of Kickapoo Indians or Kickapoo Tribe of Oklahoma, a Form I–872 American Indian Card. *See* 8 CFR 235.1(h)(1)(iii) and (v). Mexican nationals entering the United States with a BCC or with a Form I–872 may remain in the border zone for up to 30 days without having to obtain a Form I–94. Mexican nationals entering the United States with a passport and visa may remain in the border zone for up to 72 hours without having to obtain an I–94.

Mexican nationals traveling beyond these specified zones, or who will remain beyond the time periods indicated above or seek entry for purposes other than as a temporary visitor for business or pleasure, are required to obtain and complete a Form I–94. At land border ports of entry, the Form I–94 issuance process requires a secondary inspection that includes review of travel documents, examination of belongings, in-depth interview, database queries, collection of biometric data, and collection of a $6 fee. A Form I–94 issued at a land border is generally valid for multiple entries for six months.

The majority of Mexican nationals who are exempt from the Form I–94 requirement possess and apply for admission to the United States with a BCC. To obtain a BCC, applicants must be vetted extensively by the Department of State (DOS). The vetting process includes collection of information, such as fingerprints, photographs, and other information regarding residence, employment and reason for border crossing, and an interview, as well as security checks to identify any terrorism concerns, disqualifying criminal history, or past immigration violations. The BCC includes many security features such as vicinity-read Radio Frequency Identification (RFID) technology and a machine-readable zone. Using these features, CBP is able to electronically authenticate the BCC and compare the biometrics, photo and fingerprints of the individual presenting the BCC against DOS issuance records in order to confirm that the document is currently valid and that the person presenting the document is the one to whom it was issued.

[2] Effective October 2, 2002, the Form DSP–150, B–1/B–2 Visa and Border Crossing Card became the border crossing card valid for entry into the United States. *See* 67 FR 71443. The BCC is an approved document to establish identity and citizenship at the border and also serves as a B–1/B–2 visitor's visa.

Notice of Proposed Rulemaking

On August 9, 2012, CBP published an NPRM in the **Federal Register** (77 FR 47558) proposing to amend the DHS regulations to expand the zone in which Mexican nationals presenting certain documentation may travel in New Mexico without having to obtain a Form I–94. Although the border zone was intended to promote the economic stability of the border region by allowing for freer flow of travel for Mexican visitors with secure documents, New Mexico has no metropolitan areas and few tourist attractions within 25 miles of the border and thus benefits very little from the current 25-mile border zone. In order to facilitate commerce, trade, and tourism in southern New Mexico, while still ensuring that sufficient safeguards are in place to prevent illegal entry to the United States, CBP proposed extending the border zone in New Mexico from 25 miles to 55 miles from the U.S.-Mexico border.

With the extension of the border zone to 55 miles, Mexican nationals meeting the requirements for legal entry into the United States would be able to travel to metropolitan areas in New Mexico, such as the city of Las Cruces or the smaller towns of Deming and Lordsburg, and other destinations, without having to leave their vehicle and wait in line to undergo the additional Form I–94 application process at secondary inspection. This extension would not affect the 30-day time limit of the border zone applicable to BCC holders or the 72-hour time limit of the border zone applicable to Mexican nationals presenting a visa and passport.

Additionally, while the extension of the border zone to 55 miles from the U.S.-Mexico border includes most of Interstate Highway I–10, there is a short stretch of Interstate Highway I–10 that is outside the 55-mile zone. Thus, to facilitate travel, CBP proposed a provision to include all of Interstate Highway I–10 in the state of New Mexico in addition to the extension to 55 miles from the border.

The NPRM also proposed two technical corrections to § 235.1 of title 8 CFR. First, in paragraph (h)(1)(iii), CBP proposed correcting the paragraph citation from (f)(1)(v) to (h)(1)(v), as this citation was inadvertently not changed when paragraph (f) was redesignated as paragraph (h) by the Western Hemisphere Travel Initiative (WHTI) air final rule (71 FR 68412). Second, CBP proposed updating several references to § 212.1 of title 8 CFR to reflect changes contained in the WHTI land and sea final rule (73 FR 18384).

The background section of the NPRM provides more detailed information on the proposed extension, the history and development of the border zone, the BCC and its uses, and the proposed technical corrections. The NPRM provided a 60-day public comment period.

Discussion of Comments

CBP received 40 comments[3] during the comment period, all of which addressed the proposed expansion of the border zone. No comments were received on the proposed technical corrections. All but two of the comments were in favor of the proposal. Those commenters supporting the expansion of the border zone included state and local law enforcement agencies and elected officials of the region, as well as individual citizens and many other stakeholders in the business and academic communities. The two comments opposing the expansion were both from individuals.

Many of the commenters who support the proposal stated that the expanded border zone will maintain security of the border while increasing economic activity in New Mexico's border region. Some noted that the current geographic limitation on BCC holders limits commerce in a relatively impoverished region. Many commenters were of the view that the 25-mile border zone is antiquated and places the region at a competitive disadvantage compared to border regions in neighboring states. Many also stated that the region experiences high levels of unemployment and poverty, and believed that the extension of the border zone would stimulate the local economy by increasing sales, creating or saving jobs, and bolstering tax revenues. One commenter noted that local agencies with bi-national cooperation agreements are hindered in their work by the limited border zone, and often travel to El Paso for meetings rather than inviting their Mexican counterparts to join them in Las Cruces due to the additional paperwork. A few commenters stated that when the border zone was expanded in Arizona in 1999, retail sales in the area increased and the region experienced a boost in its economy. These commenters were of the view that the same boost would occur in New Mexico if the border zone is expanded there.

Many commenters, including local police and sheriff departments, stated that the expansion would have no

[3] Four of the comments were from one person who sent four separate letters in different capacities.

negative effect on security in the region. A few commenters also noted that the expansion of the zone would increase efficiency of the admission process and allow CBP to focus greater attention on securing the border from illegal entries. A few commenters stated that the expansion of the border zone will foster goodwill with the Mexican communities on the other side of the border.

CBP received comments in support of the proposal from a state senator and a state representative from New Mexico who both noted that the New Mexico Senate and House of Representatives passed a resolution in 2011 in support of extending the border zone, with unanimous and bipartisan support. CBP also received a comment in support of the proposal from Senators Bingaman and Udall and Congressman Pearce of New Mexico. The U.S. Senators and Congressman stated that the expansion of the border zone will result in increased efficiency by allowing low-risk visitors the opportunity to travel to New Mexico to shop, visit family, and conduct business while maintaining border security.

Two commenters opposed the extension of the border zone due to concerns relating to security. They are concerned that extending the border zone would result in increased illegal crossings into the United States and would lead to an increase in criminal activity in the area. One of the commenters is concerned that the extension of the border zone would increase traffic from Mexico and that this would result in decreased scrutiny of aliens entering the United States at the border, which may increase illegal activity.

Response to Comments

CBP has been very mindful of the potential impact of the extension on local law enforcement efforts as well as the impact to agencies responsible for enforcing the immigration laws along the southwest border. However, CBP believes that the extension of the border zone in New Mexico will not increase illegal crossings or illegal activity in the area. The extension of the border zone will not affect the current visa requirements for foreign nationals wishing to enter the United States nor will it affect the threshold requirements for admission into the United States as a nonimmigrant B–1/B–2 BCC [4] or B visa holder, including residence abroad and no intent to abandon that residence, intent to visit temporarily for business or pleasure, and eligibility based on applicable statutory and regulatory requirements. Travelers remain subject to questioning regarding intent and purpose of travel during inspection upon arrival in the United States. CBP Officers are able to verify at the ports of entry through biometric matching (photo and/or fingerprints) that the individual presenting a BCC is the authorized holder and, by comparison against DOS's issuance records in a shared database, that the document is valid. The existing use of Border Patrol checkpoints within 100 miles of the border serve as a second tier of enforcement deterring the further movement of illegal immigration to the interior of the United States.

CBP notes that law enforcement officials in some of the affected areas, including the Chiefs of Police of the cities of Las Cruces, Deming, and Lordsburg, the Sheriffs of Hidalgo and Luna Counties, and the Marshal of the town of Mesilla each stated in their comments that no negative law enforcement ramifications were anticipated.

CBP believes that the expanded border zone will allow CBP to better allocate its resources while enhancing its enforcement posture. The expanded border zone will reduce the number of Mexican nationals required to obtain a Form I–94 and thus will increase CBP's administrative efficiency by reducing unnecessary paperwork burdens associated with the Form I–94 process and allowing CBP to reallocate that staff time to other security enhancing activities.

CBP anticipates that the extension of the border zone will encourage Mexican nationals visiting New Mexico to use the BCC, which will further enhance security in the region. The BCC is CBP's preferred method of identification for Mexican nationals entering the United States at land border ports of entry. The BCC is one of the most secure travel documents used at the border, and BCC holders undergo extensive vetting by CBP and DOS. BCCs contain numerous, layered security features, such as enhanced graphics and technology, that provide protection against fraudulent use. Using existing technology, CBP can very quickly verify the validity of the card, the identity of the cardholder, and other pertinent information about the cardholder. The use of a BCC card has increased security in processing travelers by allowing the ability to affirmatively identify the individual and conduct admissibility checks.

CBP also anticipates that the expansion of the border zone will enhance security due to the time savings from an increased use of the BCC, which enables CBP to identify more quickly whether travelers present a risk, and allows CBP to reallocate resources that would have been used for processing these travelers to processing for higher risk individuals, both at ports of entry and inland immigration checkpoints. Inspections at the border will remain thorough, but the increased use of travel documents containing RFID technology, such as the BCC, will contribute to reducing individual inspection processing time. Law enforcement queries regarding travelers with RFID travel documents, such as the BCC, are 20 percent faster than for persons with documents containing only a machine-readable zone, and 60 percent faster than manual entry of information from a paper document.[5] The use of RFID technology in the BCC enables CBP to more quickly authenticate the documents, and thus helps CBP more quickly assess whether the traveler presents a risk. Greater use of RFID travel documents such as the BCC will allow CBP to focus its personnel time on higher risk individuals while providing efficiencies in the flow of legitimate trade and travel in the area. CBP anticipates that any delays resulting from the increase in traffic will be offset by more efficient processing and better use of officers assigned to the port of entry.

Adoption of the Proposal

After review of the comments, CBP has determined to adopt as final the proposed rule published in the **Federal Register** to extend the border zone in New Mexico and to adopt the proposed technical corrections to 8 CFR 235.1. A map of the expanded border zone can be found in the docket for this rulemaking (docket number USCBP–2012–0030) on *www.regulations.gov.*

Authority

These regulations are being amended pursuant to 8 U.S.C. 1101, 1103, 1185, 1185 note, and 1225.

Statutory and Regulatory Requirements

Executive Order 12866 (Regulatory Planning and Review) and Executive Order 13563 (Improving Regulation and Regulatory Review)

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory

[4] The BCC can be used as both a Border Crossing Card and also as a B–1/B–2 visa. The full name of the document is ''Form DSP–150, B–1/B–2 Visa and Border Crossing Card.'' *See* 8 CFR 212.1(c)(1)(i).

[5] Statistics derived from operational data stored in TECS, the official system of record for CBP operational and enforcement data.

approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule is a ''significant regulatory action,'' although not an economically significant regulatory action, under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has reviewed this regulation.

Mexican nationals entering the United States in New Mexico at land border ports of entry are required to present a BCC or a passport and a visa in order to be admitted to the United States. Visitors intending to travel beyond the border zone, or longer than 30 days (72 hours for certain individuals) are also required to obtain a Form I–94 and use it in conjunction with their BCC or passport and visa. Currently, if the traveler is admitted using a passport and visa, he or she is only able to travel up to 25 miles from the U.S.-Mexico border in New Mexico and remain in the United States for up to 72 hours without obtaining a Form I–94; if the traveler is admitted using a BCC, he or she is able to travel up to 25 miles from the border and stay for up to 30 days without obtaining a Form I–94. Travelers who obtain a Form I–94 are able to travel anywhere in the United States and stay for up to six months.[6]

However, in practice, travelers generally either enter the United States with a BCC and stay within the border zone or obtain a Form I–94, for use with a passport and visa or with a BCC, to go beyond the border zone. In 2011, about 900,000 Mexican nationals entered the United States in New Mexico. About sixty percent, or 540,000, of these travelers used a BCC. The remainder, 360,000, entered using a Form I–94 with their passport and visa. There were approximately 136,000 Form I–94s issued to Mexican nationals at New Mexico land border ports in 2011. Multiple trips are allowed during the Form I–94's validity period, which accounts for the difference in the total number of Form I–94 crossings and the total number of Form I–94's issued.

Costs

This final rule expands the geographic limit for BCC holders traveling in New Mexico who have not obtained a Form I–94. Under existing regulations, BCC holders can travel anywhere within 25 miles of the border without obtaining a Form I–94. This rule allows BCC holders to travel anywhere in New Mexico within 55 miles from the U.S.-Mexico border or as far north as Interstate Highway I–10, whichever is farther north, without obtaining a Form I–94. No new infrastructure is required to support this change, as CBP already has several ports of entry and inland immigration checkpoints in place throughout New Mexico. In addition, federal, state, and local law enforcement officials have indicated that they do not anticipate any security risks with expanding the geographic limit. Given these observations, CBP does not anticipate any significant costs associated with this final rule. CBP sought comments on the possibility of additional costs associated with this rule, but did not receive any.

Benefits

This expanded border zone will allow Mexican BCC holders to travel to many New Mexico destinations that currently require a Form I–94 to access, including several cities, state parks, and a major university. To the extent that BCC holders are obtaining Form I–94s for the purpose of visiting destinations within the expanded border zone, there will be fewer Form I–94s that will need to be completed as a result of this final rule, generating both time and cost savings for Mexican nationals and CBP Officers. At land borders, the Form I–94 application process is completed at the port of entry at secondary inspection and includes an interview with a CBP Officer, fingerprinting, electronic vetting, paperwork, and the payment of a $6 fee. CBP estimates that this process takes eight minutes to complete. CBP maintains two ports of entry along the Mexican border in New Mexico—Columbus and Santa Teresa. Between 2010 and 2011, the port of Columbus issued an average of approximately 27,000 Form I–94s per year, and the port of Santa Teresa issued an average of approximately 114,000 Form I–94s per year. CBP does not know how many of the travelers who are now required to obtain these forms will benefit from the expanded geographic limit, but believes that the percentage benefitting from this final rule will be less than 25 percent. CBP sought comments on this assumption, but did not receive any. CBP believes the percentage will be significantly lower for crossings at Santa Teresa because those crossings are predominantly bound for El Paso, which is already within the current 25-mile border crossing card limit. CBP sought comments on this assumption, but did not receive any. Eliminating the need for these travelers to leave the vehicle to undergo the additional Form I–94 application process at secondary inspection and pay the $6 fee could be a significant savings for Mexican travelers who are affected, and could benefit the travel and tourism industry in the U.S.-Mexico border zone. CBP sought comments on the possible savings for Mexican travelers who would no longer complete the Form I–94, but did not receive any. CBP will not be adversely affected by this loss in Form I–94 fee revenue because this fee revenue is used exclusively to pay for the processing of the Form I–94. Therefore, the reduction in revenue will be offset by a reduction in workload.

Because this rule will make it unnecessary for some travelers to obtain a Form I–94, CBP will be able to inspect travelers more efficiently and focus its efforts on higher risk individuals. CBP expects this increase in efficiency to more than offset any new workload caused by a small increase in travelers to the United States that may result from this final rule. CBP may experience additional time savings from this rule with the increased use of BCCs as border crossing documents. The BCC is one of the most secure travel documents used at the border and allows for faster processing at both the port of entry and interior immigration checkpoints. BCCs contain numerous, layered security features, such as enhanced graphics and technology, that provide protection against fraudulent use. Moreover, BCC holders undergo extensive vetting by CBP and DOS. Using existing technology, CBP can very quickly verify the validity of the card, the identity of the cardholder, and other pertinent information about the cardholder. A faster inspection will allow CBP to spend more time inspecting higher risk individuals and could therefore improve security. Several commenters agreed with this conclusion.

Perhaps the greatest benefit of this final rule is the potential for increased economic activity in New Mexico's border region. According to the U.S. Census Bureau's American Community Survey, the estimated poverty rate for the United States in 2006–2010 was 13.8 percent.[7] For the three counties most affected by this change— Doña Ana, Hidalgo, and Luna—the American Community Survey estimates poverty rates of 24.5 percent, 22.6 percent, and

[6] See 8 CFR 235.1(h)(1)(iii) and (v); 8 CFR 212.1(c).

[7] U.S. Census Bureau, American Community Survey five-year estimate (2006 to 2010), table S1701. This data can be queried via the American Fact Finder database located at *http://factfinder2.census.gov/faces/nav/jsf/pages/searchresults.xhtml?refresh=t.*

32.8 percent, respectively. Under existing regulations, main population centers like Las Cruces, New Mexico and other smaller cities in Doña Ana, Hidalgo, and Luna Counties are at a disadvantage in attracting travelers from Mexico because they are outside of the 25-mile border zone. In contrast, many main population centers along the Arizona and Texas borders are within border zone limits (75 miles in Arizona and 25 miles in Texas) and offered more shopping and recreation opportunities for Mexican travelers than New Mexico border zone areas. Such limited travel and tourism opportunities in New Mexico's 25-mile border zone create significant disincentives for Mexican visitors to engage in commerce in New Mexico rather than its neighboring states. This border expansion will increase the number of shopping and recreation options in New Mexico for Mexican travelers, which may spur economic growth in this rule's affected regions. Under existing border zone regulations, visitors from Mexico also face road travel limitations. BCC holders can travel much of the Interstate Highway I–10 corridor in Arizona, but are prevented from continuing into New Mexico unless they have a Form I–94. This rule expands the border zone enough to allow BCC holders to travel on Interstate Highway I–10 from Tucson, Arizona to Las Cruces, New Mexico and El Paso, Texas, benefitting commerce in the entire region. CBP received comments in support of this assumption, as outlined in the ''Discussion of Comments'' section. This regulatory action is expected to increase access to U.S. markets for Mexican travelers and is expected to result in increased travel through the New Mexico border region, which will lead to increased sales, employment, and local tax revenue. CBP received a number of comments on the possible benefits of expanding the U.S.-Mexico border zone. Many commenters stated that New Mexico communities within the expanded border zone would gain increased sales, jobs, and tax revenue due to rises in Mexican tourists. A few commenters also asserted that the border expansion would allow Mexican nationals to visit family members and medical facilities once outside of the zone limits. These comments are discussed in more detail in the ''Discussion of Comments'' section above.

Net Impact

In summary, by expanding the border zone for BCC holders, this rule will not impose any new costs on the public or on the United States government. Further, this rule is expected to reduce costs to Mexican visitors to the United States, improve security, and benefit commerce in a relatively impoverished region. The majority of comments that CBP received supported this conclusion. These comments are discussed in more detail in the ''Discussion of Comments'' section above.

The Regulatory Flexibility Act

This section examines the impact of the rule on small entities as required by the Regulatory Flexibility Act (5 U.S.C. 601 et. seq.), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

This rule directly regulates individuals rather than small entities. In addition, this rule is purely beneficial to these individuals as it expands the area BCC holders may travel without needing to obtain a Form I–94. As explained above, CBP is not aware of any direct costs imposed on the public by expanding the geographic limit for BCC holders but is aware of a cost savings for the traveling public by expanding the geographic limit. CBP sought comment on this conclusion but did not receive any. Accordingly, DHS certifies that this rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

An agency may not conduct, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by OMB. CBP's form that is affected by this rule is the Form I–94 (Arrival/Departure Record). CBP anticipates that this rule will result in a slight decrease in the number of Form I–94s filed annually. The Form I–94 was previously reviewed and approved by OMB in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under OMB Control Number 1651–0111.

This rule would result in an estimated reduction of 12,450 Forms I–94 completed by paper, and an estimated reduction of 1,656 burden hours. The remaining estimated burden associated with the Form I–94 is as follows:

Estimated Number of Respondents: 4,387,550.

Estimated Number of Total Annual Responses: 4,387,550.

Estimated Time per Response: 8 minutes.

Estimated Total Annual Burden Hours: 583,544.

List of Subjects in 8 CFR Part 235

Administrative practice and procedure, Aliens, Immigration, Reporting and recordkeeping requirements.

Amendments to the Regulations

For the reasons set forth in the preamble, CBP is amending 8 CFR part 235 as set forth below.

PART 235—INSPECTION OF PERSONS APPLYING FOR ADMISSION

■ 1. The general authority citation for part 235 continues to read as follows:

Authority: 8 U.S.C. 1101 and note, 1103, 1183, 1185 (pursuant to E.O. 13323, 69 FR 241, 3 CFR, 2004 Comp., p.278), 1201, 1224, 1225, 1226, 1228, 1365a note, 1365b, 1379, 1731–32; Title VII of Pub. L. 110–229; 8 U.S.C. 1185 note (section 7209 of Pub. L. 108–458).

■ 2. In § 235.1, revise paragraphs (h)(1)(iii) and (h)(1)(v)(A) and (B) and add paragraphs (h)(1)(v)(C) and (D) to read as follows:

§ 235.1 Scope of examination.

* * * * *

(h) * * *

(1) * * *

(iii) Except as provided in paragraph (h)(1)(v) of this section, any Mexican national admitted as a nonimmigrant visitor who is:

(A) Exempt from a visa and passport pursuant to § 212.1(c)(1) of this chapter and is admitted for a period not to exceed 30 days to visit within 25 miles of the border; or

(B) In possession of a valid visa and passport and is admitted for a period not to exceed 72 hours to visit within 25 miles of the border;

* * * * *

(v) * * *

(A) Exempt from a visa and passport pursuant to § 212.1(c)(1) of this chapter and is admitted at the Mexican border POEs in the State of Arizona at Sasabe, Nogales, Mariposa, Naco or Douglas to visit within the State of Arizona within 75 miles of the border for a period not to exceed 30 days; or

(B) In possession of a valid visa and passport and is admitted at the Mexican border POEs in the State of Arizona at Sasabe, Nogales, Mariposa, Naco or Douglas to visit within the State of Arizona within 75 miles of the border for a period not to exceed 72 hours; or

(C) Exempt from visa and passport pursuant to § 212.1(c)(1) of this chapter

and is admitted for a period not to exceed 30 days to visit within the State of New Mexico within 55 miles of the border or the area south of and including Interstate Highway I–10, whichever is further north; or

(D) In possession of a valid visa and passport and is admitted for a period not to exceed 72 hours to visit within the State of New Mexico within 55 miles of the border or the area south of and including Interstate Highway I–10, whichever is further north.

* * * * *

Janet Napolitano,

Secretary.

[FR Doc. 2013–13946 Filed 6–11–13; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 29

[Docket No. FAA–2013–0502; Special Conditions No. 29–030–SC]

Special Conditions: Eurocopter France, EC175B; Use of 30-Minute Power Rating

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions; request for comments.

SUMMARY: These special conditions are issued for the Eurocopter France Model EC175B helicopter. This model helicopter will have the novel or unusual design feature of a 30-minute power rating, generally intended to be used for hovering at increased power for search and rescue missions. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is June 3, 2013. We must receive your comments by July 29, 2013.

ADDRESSES: Send comments identified by docket number FAA–2013–0502 using any of the following methods:

- *Federal eRegulations Portal:* Go to *http://www.regulations.gov* and follow the online instructions for sending your comments electronically.
- *Mail:* Send comments to Docket Operations, M–30, U.S. Department of Transportation (DOT), 1200 New Jersey Avenue SE., Room W12–140, West Building Ground Floor, Washington, DC, 20590–0001.
- *Hand Delivery of Courier:* Take comments to Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 8 a.m., and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* Fax comments to Docket Operations at 202–493–2251.

Privacy: The FAA will post all comments it receives, without change, to *http://regulations.gov,* including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477–19478), as well as at *http://DocketsInfo.dot.gov.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room @12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m., and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Eric Haight, Rotorcraft Standards Staff, ASW–111, Rotorcraft Directorate, Aircraft Certification Service, 2601 Meacham Blvd., Fort Worth, Texas 76137; telephone (817) 222–5204; facsimile (817) 222–5961.

SUPPLEMENTARY INFORMATION:

Reason for No Prior Notice and Comment before Adoption

The FAA has determined that notice and opportunity for public comment are impractical because we do not expect substantive comments, and because this special condition only affects this one manufacturer. We also considered that these procedures would significantly delay the issuance of the design approval, and thus, the delivery of the affected aircraft. As certification for the Eurocopter France model EC175B is imminent, the FAA finds that good cause exists for making these special conditions effective upon issuance.

Comments Invited

While we did not precede this with a notice of proposed special conditions, we invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive by the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

Background and Discussion

On March 10, 2008, Eurocopter France applied for a Type Certificate for the new model EC175B. The EC175B is a Transport Category, 14 CFR part 29, twin engine conventional helicopter designed for civil operations. This model will be certificated with Category A performance and under dual pilot instrument flight rules, powered by two Pratt & Whitney PT6C–67E engines with a dual channel Full Authority Digital Engine Control system, have five main rotor blades, a maximum gross weight of 15,400 pounds, and a velocity not to exceed 175 knots. The EC175B model will have an integrated modular avionics suite with four 6x8 inch multi-function displays termed the Common Integrated Global Avionics for Light Helicopters. This rotorcraft will be capable of carrying 16 passengers and 2 crew members. Its initial customer base will be offshore oil and Search and Rescue operations.

Eurocopter France proposes that the EC175B model use a novel and unusual design feature, which is a 30-minute power rating, identified in the Pratt & Whitney Canada PT6C–67E engine type certificate data sheet (TCDS) [FAA TCDS No. E00068EN]. 14 CFR 1.1 defines ''rated takeoff power'' as limited in use to no more than 5 minutes for takeoff operation. Thus, the use of takeoff power for 30 minutes will require special airworthiness standards, known as special conditions, to address the use of this 30-minute power rating and its effects on the rotorcraft. The use of this power will be limited to 50 minutes per flight based on engine durability considerations. These special conditions will add requirements to the existing airworthiness standards in 14 CFR 29.1049 (Hovering cooling test procedures), § 29.1305 (Powerplant instruments), and § 29.1521 (Powerplant limitations).

For the EC175B, the European Aviation Safety Agency has issued CRI E–01, which documents the special conditions.

The following is a summary of the final special conditions:

In addition to the requirements of § 29.1049, the aircraft cooling effects due to use of the 30-minute power rating must be accounted for in the testing.

In addition to the requirements of § 29.1305, since this new 30-minute power rating has a time limit associated with its use, the pilot must have the means to identify:

- When the rated engine power level is achieved,
- When the event begins,
- When the time interval expires, and
- When the cumulative time in one flight is reached.

In addition to the requirements of § 29.1521, Powerplant Limitations, the use of takeoff power for 30 minutes must be limited to not more than 30 minutes per use and no more than 50 minutes per flight. This is based upon the definition of ''rated takeoff power'' in 14 CFR 1.1, which limits the use of rated takeoff power to periods of not over 5 minutes for takeoff operation.

Furthermore, the Model EC175B rotorcraft flight manual must include limitations on use of the 30-minute power rating to state:

- Continuous use above maximum continuous power (MCP) is limited to 30 minutes, and
- Cumulative use above MCP is limited to 50 minutes per flight.

Type Certification Basis

Under 14 CFR 21.17, Eurocopter France must show that the EC175B model helicopter meets the applicable provisions of part 29, as amended by Amendment 29–1 through 29–52, dated April 5, 2010. In addition, the certification basis includes certain later amended sections of part 29 that are not relevant to these special conditions.

The Administrator has determined that the applicable airworthiness regulations (that is, 14 CFR part 29) do not contain adequate or appropriate safety standards for the EC175B model helicopter because of a novel or unusual design feature. Therefore, special conditions are prescribed under the provisions of 14 CFR 21.16.

In addition to the applicable airworthiness regulations and special conditions, the EC175B must comply with the noise certification requirements of 14 CFR part 36; and the FAA must issue a finding of regulatory adequacy under section 611 of Public Law 92–574, the ''Noise Control Act of 1972.''

The FAA issues special conditions, as defined in § 11.19, in accordance with § 11.38, and they become part of the type certification basis under § 21.17(a)(2).

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, the special conditions would also apply to the other model.

Novel or Unusual Design Features

The EC175B model helicopter will incorporate a novel or unusual design feature, which is:

- A 30-minute power rating.

Applicability

These special conditions are applicable to the Eurocopter France model EC175B helicopter. Should Eurocopter France apply at a later date for an amendment to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Conclusion

This action affects only certain novel or unusual design features on the Eurocopter France model EC175B helicopter. It is not a rule of general applicability, and it affects only the applicant who applied to the FAA for approval of this feature.

List of Subjects in 14 CFR Part 29

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701–44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Eurocopter France model EC175B helicopter. Unless stated otherwise, all requirements in §§ 29.1049, 29.1305, and 29.1521 remain unchanged.

(a) Section 29.1049 Hovering cooling test procedures, Final Rule. Docket No. 5084; issued October 13, 1964. In addition to the requirements of this section, the special condition states:

''The hovering cooling provisions at the 30-minute power rating must be shown—

(a) At maximum weight or at the greatest weight at which the rotorcraft can hover (if less), at sea level, with the power required to hover but not more than the 30-minute power, in the ground effect in still air, until:

- At least 5 minutes after the occurrence of the highest temperature recorded; or
- the continuous time limit of the 30-minute power rating if the highest temperature recorded is not stabilized before.

(b) At maximum weight, and at the altitude resulting in zero rate of climb for this configuration, until:

- At least 5 minutes after the occurrence of the highest temperature recorded; or
- the continuous time limit of the 30-minute power rating if the highest temperature recorded is not stabilized before.''

(b) Section 29.1305 Powerplant instruments, at Amendment 29–40. In addition to the requirements of this section, the special condition is similar to § 29.1305(a)(25) for the 30-minute power rating and states:

''For rotorcraft with a 30-minute power rating, a means must be provided to alert the pilot when the engine is at the 30-minute power level, when the event begins, when the time interval expires, and when the cumulative time in one flight is reached.''

(c) Section 29.1521 Powerplant limitations, at Amendment 29–41. In addition to the requirements of this section, the special condition is similar to § 29.1521(b) and states:

''Use of the 30-minute power must be limited to no more than 30 minutes per use, and no more than 50 minutes per flight. The use of the 30-minute power must also be limited by:

(1) The maximum rotational speed, which may not be greater than—

(i) The maximum value determined by the rotor design; or

(ii) The maximum value demonstrated during the type tests;

(2) The maximum allowable turbine inlet or turbine outlet gas temperature (for turbine engines);

(3) The maximum allowable power or torque for each engine, considering the power input limitations of the transmission with all engines operating;

(4) The maximum allowable power or torque for each engine considering the power input limitations of the transmission with one engine inoperative;

(5) The time limit for the use of the power corresponding to the limitations established in paragraphs (b)(1) through (5) of this section; and

(6) If the time limit established in paragraph (b)(6) of this paragraph exceeds 2 minutes—

(i) The maximum allowable engine and transmission oil temperatures.''

Issued in Fort Worth, Texas on June 3, 2013.

Kimberly K. Smith,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2013–13800 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2012–0983; Directorate Identifier 2012–CE–001–AD; Amendment 39–17457; AD 2013–10–04]

RIN 2120–AA64

Airworthiness Directives; Piper Aircraft, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are superseding an existing airworthiness directive (AD) for all Piper Aircraft, Inc. Models PA–31, PA–31–325, and PA–31–350 airplanes. That AD currently requires a detailed repetitive inspection of the exhaust system downstream of the turbochargers and repair or replacement of parts as necessary. This new AD requires visual repetitive inspections, expanding the inspection scope to include the entirety of each airplane exhaust system. This AD was prompted by reports of exhaust system failures upstream of aircraft turbochargers and between recurring detailed inspections. We are issuing this AD to correct the unsafe condition on these products.

DATES: This AD is effective July 17, 2013.

The Director of the Federal Register approved the incorporation by reference of certain publications listed in the AD as of July 17, 2013.

ADDRESSES: For service information identified in this AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567–4361; fax: (772) 978–6573; Internet: *www.piper.com/home/pages/Publications.cfm.* You may review copies of the referenced service information at the FAA, FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Gary Wechsler, Aerospace Engineer, Atlanta Aircraft Certification Office, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; telephone: (404) 474–5575; fax: (404) 474–5606; email: *gary.wechsler@faa.*

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 82–16–05 R1, amendment 39–5278 (51 FR 11707, April 7, 1986). That AD applies to the specified products. The NPRM published in the **Federal Register** on September 18, 2012 (77 FR 57534). The NPRM included a detailed inspection that involved disassembling the v-band couplings. We removed that detailed inspection, and we added a table listing specific parts and inspection criteria to clarify the visual inspection. We also identified that airplanes with the STC SA240CH heat exchanger installed may not have all of the parts requiring the visual inspection. (Information on STC SA240CH may be found at *http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/30C512E870BE421D86257297005B6822?OpenDocument&Highlight=sa240ch.*) We determined that these changes will not increase the economic burden on any operator or increase the scope of the AD over what was originally proposed in the NPRM.

Comments

We gave the public the opportunity to participate in developing this AD. The following presents the comments received on the proposal and the FAA's response to each comment.

Revise Cost of Compliance

Douglas Deering and Terry Mangione stated the compliance costs are too high and could lead to cost saving attempts in other places. Douglas Deering added the cost does not include clamps and gaskets.

We partially agree. We agree that the cost of compliance per airplane may vary depending on the location in which compliance is made because the cost of labor and parts varies throughout the United States of America. We disagree with the claim that the cost of compliance is too great because of the safety risk the current design poses. Additionally, the cost of replacing clamps and gaskets is part of the on-condition costs, which cannot be predicted because of the multitude and manner of environments in which these airplanes operate result in widely varying exhaust system conditions over time.

We did not make any changes to this final rule AD action as a result of this comment.

Eliminate or Change Visual Inspection Compliance Requirement

Douglas Deering, Joe Miller, and Lycoming Engines suggested eliminating the visual inspection compliance requirement and instead visually inspecting the entire exhaust system at 100 hours time-in-service (TIS) or every other engine inspection event if maintained by an FAA-approved aircraft inspection program (AAIP). Visual inspections are already required under AAIP, 100-hour, and annual inspections; and Lycoming engine operations manuals currently recommend 50-hour visual inspections of the entire exhaust manifold for leaks.

We agree that manufacturer's maintenance instructions include visual inspection requirements for exhaust and turbocharger systems. However, these manufacturer's maintenance instructions are only recommendations from which operators may base individual, FAA approved, maintenance programs on. Thus, AAIP, 100-hour, and annual inspection programs may or may not include the inspections proposed by this AD. The only way to ensure that a level of maintenance is performed to mitigate the safety risk the current design poses is through mandating these inspections, hence the need for the AD.

We disagree with the request to eliminate the recurring 50-hour visual inspection compliance requirement because a visual inspection to look for specific signs of imminent failure at intervals less than 100 hours was determined necessary to mitigate the safety risk the current design poses. The inspections required by AAIP, 100-hour and annual inspections, and Lycoming engine manual requirements do not mitigate the unsafe condition identified in this AD.

We changed this final rule AD action to clarify the visual inspection process. We added a table of part numbers requiring inspection and the signs of

imminent failure to inspect for on these parts (and referenced a source of pertinent methods). Also, we expanded the visual inspection interval from 50 hours to 60 hours TIS in an attempt to encompass operators with FAA-approved inspection plans without an adverse effect to inspection effectiveness.

Eliminate Calendar Time Limited Inspection Intervals

Douglas Deering, Allen M. Bower, and AMBO Ltd. stated we should eliminate the calendar time inspection interval limits for the compliance requirements because they do not believe calendar time outside of usage could adversely affect exhaust system integrity. Allen M. Bower, and AMBO Ltd. cited Special Airworthiness Information Bulletin (SAIB) CE–00–16, dated February 4, 2000, dealing with the twin Cessna exhaust system, as an example of a safety action that does not require calendar time inspection limits, ''You do not have to accomplish any action toward the AD until 2,500 hours TIS have accumulated on the exhaust system or exhaust system components.''

We do not agree because the 6-month inspection requirement is necessary to check for the effects of corrosion that can occur while an aircraft is not in service. The level of exhaust system corrosion that can occur over a 6-month period is largely dependent on environmental conditions (higher moisture, temperature, and salinity lead to higher corrosion rates), exhaust material surface condition (higher levels of oxidation and scratches lead to higher corrosion rates,) and material geometry and assembly (crevices created by mating part surfaces and tight cracks corrode faster than open surfaces.)

The AD, 2000–01–16 (65 FR 2844, January 19, 2000), cited by the SAIB referenced above, clearly requires actions before 2,500 hours TIS via the statements listed within that AD's figure 1, Compliance Table, of which several are paraphrased here: Visually inspect exhaust systems within 50 hours TIS after the effective date of the AD or within the next 30 calendar days, whichever occurs later; remove tailpipes and visually inspect for any crack, corrosion, holes, or distortion upon the accumulation of 5 years since installing a new or overhauled exhaust system or within the next 100 hours TIS after the effective date of this AD, whichever occurs later; and, inspect and pressure test exhaust systems upon the accumulation of 5 years since installing a new or overhauled exhaust system or within the next 100 hours TIS after the effective date of the AD, whichever occurs later. In summary, AD 2000–01–06 (65 FR 2844, January 19, 2000) requires exhaust inspections with a calendar time limit for their intervals, before 2,500 hours TIS.

We did not make any changes to this final rule AD action as a result of this comment.

Limit Compliance to One Manufacturer

Douglas Deering stated that we should limit compliance requirements to a single exhaust system manufacturer because recent exhaust pipe flange failures were due to a single manufacturer.

We do not agree because the FAA has not concluded the root cause of recent exhaust pipe flange failures is due to a single exhaust pipe manufacturer.

We did not make any changes to this final rule AD action as a result of this comment.

Discuss Exhaust System Misalignment, Its Effect on Exhaust System Failures, and Pertinent Company Service Information

Douglas Deering and Acorn Welding stated that we should mention exhaust parts fail at flanges due to exhaust assembly misalignment created by improper assembly, mis-manufactured parts, and/or slip joint seizing. They state exhaust system installation should be in accordance with Lycoming Service Instruction 1320, dated March 7, 1975, and Lycoming Service Instruction 1391, dated October 5, 1979; v-band coupling installation should be in accordance with Lycoming Service Instruction 1238B, dated January 6, 2010, and exhaust system improvements should be required per Lycoming Service Instruction 1410, dated June 19, 1981. They recommended Lycoming service instructions that address practices and assemblies meant to address the aforementioned problems.

We agree that exhaust assembly misalignment due to improper exhaust system assembly, mis-manufacturing, and/or slip joint seizures can contribute to and/or cause the cracking of exhaust pipe flanges because of excessive eccentric loading. We disagree with requiring exhaust system improvements per Lycoming Service Instruction 1410, dated June 19, 1981, because the events that prompted this AD were not documented as due to the absence of the slip joint introduced by this service instruction. Also, Lycoming Service Instruction 1238B, dated January 6, 2010, is referenced elsewhere in the proposed AD with regards to v-band coupling installation.

We changed this final rule AD action to clarify the repair/replacement process. We changed paragraph (i)(1)(ii) (which is now (h)(1)(ii)) to read: ''Repair or replace exhaust system parts exhibiting bulges, cracks and/or exhaust leak stains with airworthy parts in accordance with Lycoming Service Information 1320, dated March 7, 1975, and Lycoming Service Information 1391, dated October 5, 1979, as applicable.''

Reduce/Eliminate Recurring V-Band Clamp Disassembly for Inspections

Douglas Deering, Joe Miller, Terry Mangione, Lycoming Engines, Allen M. Bower, and AMBO Ltd. stated we should reduce/eliminate the frequency of inspections requiring v-band clamp disassembly because the v-band clamp disassembly subjects the v-band clamp to a high degree of stress.

We agree because v-band clamp disassembly can cause damage. Therefore, a decrease in recurrent inspection intervals requiring v-band clamp disassembly may increase the rate at which v-band clamps and/or locking nuts accumulate damage.

We changed paragraph (h) of this AD to eliminate the recurring 100-hour disassembly of v-band clamps.

Remove the Corrective Actions of Paragraph (i)

Douglas Deering stated we should remove the corrective actions contained in paragraph (i) of this AD (which has now been merged into paragraph (h)). The paragraph (i) (which is now merged into paragraph (h)) corrective actions only reinforce what any technician would be required to do upon finding defects during an exhaust system inspection.

We do not agree because we determined the corrective actions of paragraph (i) (which is now merged into paragraph (h)) were necessary to mitigate the safety risk the current design poses.

We did not make any changes to this final rule AD action as a result of this comment.

Eliminate V-Band Clamp Replacement at 1,000 TIS

Douglas Deering, Joe Miller, Acorn Welding, Allen H. Bower, and AMBO Ltd. stated we should specify which v-band clamp numbers need to be replaced at 1,000 hours TIS and delete the requirement to replace v-band clamp part numbers (P/N) 557–584 and 557–369 at 1,000 hours TIS. The installation of v-band clamps P/N 557–584 and P/N 557–369 exempts one from the detailed inspections of Part II of Piper Service Bulletin 644E, dated May 9, 2012. They state Piper Service Bulletin

644E, dated May 9, 2012, should be a template for the proposed AD. Piper Service Bulletin 644E does not require a life limit for v-band coupling P/N 557–584 and P/N 557–369 (only replacement on condition) and requires 100-hour TIS recurring inspections and 1,000-hour TIS replacement for v-band coupling P/N 555–511 and P/N 555–366. Anecdotal experience substantiates longevity of v-band coupling P/N 557–584 and P/N 557–369.

We agree because initial data indicated that the Piper v-band clamps (P/N 557–584 and P/N 557–369) connecting the turbocharger exhaust outlet flange with the tailpipe were failing with fewer hours TIS than engine time between overhaul (TBO). Further data and feedback indicates that the cases where the clamps may have failed in service, the clamps were not recovered (they were lost during the event). The clamps found cracked were found cracked during inspections.

We changed this AD to not require mandatory replacement of Piper clamps P/N 557–584 and P/N 557–369 at 1,000 hours TIS.

Remove Exhaust System Installation Steps Already Contained in Company Service Information

Douglas Deering stated that we should delete paragraphs (k)(2) and (k)(3) of this AD and make paragraph (k)(4) a note to paragraph (k). The v-band coupling installation steps defined by paragraphs (k)(2) and (k)(3) are already stated in Piper Service Bulletin 644E, dated May 9, 2012, and Lycoming Service Instruction 1238B, dated January 6, 2010, and the text of paragraph (k)(4) is not required by the AD, but might help the operator to comply with the AD.

We agree because the v-band coupling installation steps defined by paragraphs (k)(2) and (k)(3) (now (h)(2) and (h)(3)) are already stated in Piper Service Bulletin 644E, dated May 9, 2012, and Lycoming Service Instruction 1238B, dated January 6, 2010. The text of paragraph (k)(4) (now (h)(4)) is not required by the AD itself but might help the operator to comply with the AD.

We will change this AD to eliminate paragraphs (k)(2) and (k)(3) and make the text of paragraph (k)(4) part of a Note to paragraph (k) (now referred to as paragraph (h).

Change Inspection Process for Airplanes With Supplemental Type Certificate (STC) SA240CH Installations

Douglas Deering stated heat exchanger installations in accordance with STC SA240CH are not uncommon and would require an alternative method of compliance (AMOC) to the NPRM's inspection procedure. (Information on STC SA240CH may be found at *http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/30C512E870BE421D86257297005B6822?OpenDocument&Highlight=sa240ch*.) The commenter requests the NPRM inspection procedure be revised in a manner that airplanes modified per STC SA240CH will not require an AMOC.

We agree with this comment. A high percentage of airplanes have STC SA240CH installed, approximately 310 out of 508 airplanes (61 percent), and would require an AMOC to comply with the AD as written because those airplanes will not have all of the exhaust parts requiring inspection.

We added a subparagraph to paragraph (g) of this AD that eliminates the inspection for the exhaust system parts referenced above regarding the STC SA240CH heat exchanger. This allows airplanes with STC SA240CH heat exchanger installed to comply with the AD without applying for an AMOC.

Limit Exhaust System Life to Time-Between-Overhauls

Douglas Deering, Terry Mangione, and Acorn Welding stated that we should limit exhaust system life to engine TBO. Exhaust system failure rates increase quickly once exhaust life surpasses engine TBO.

We do not agree because the intent of the proposed AD is not to designate a life limit for exhaust systems. Instead, the intent of the proposed AD is to implement a 60-hour TIS recurring visual inspection to identify and correct v-band coupling and exhaust flange issues before they lead to a safety event.

We did not make any changes to this final rule AD action as a result of this comment.

Change Product Applicability

Douglas Deering and Acorn Welding stated we should change the AD applicability from Piper aircraft to include Lycoming engines TI0–540–A2C, LFFI0–540–F2BD, –J2B, –J2BD, –N2BD, and –R2BD.

We do not agree because the previous AD and this superseding AD are based on the configuration and installation of the engine on the aircraft and not the type design of the engine.

We did not make any changes to this final rule AD action as a result of this comment.

Issue an SAIB in Lieu of This AD

Lycoming Engines stated an SAIB alerting operators to the importance of the manufacturer's recommendations would be more appropriate than an AD. One clamp in data analyzed was mis-installed and should not have been included and two service difficulty reports (SDRs), by themselves, used in the FAA's analysis do not represent an increasing trend of failures substantiating the AD.

We do not agree because over the last 11 years there have been 6 exhaust system related incidents that occurred either during cruise, approach, takeoff, or climb. One incident resulted in substantial airplane damage. Risk analysis concluded the risk of an exhaust system related incident resulting in a hazard greater than substantial airplane damage for the future warranted the publication of an AD.

We did not make any changes to this final rule AD action as a result of this comment.

Conclusion

We reviewed the relevant data, considered the comments received, and determined that air safety and the public interest require adopting the AD with the changes described previously and minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (77 FR 57534, September 18, 2012) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (77 FR 57534, September 18, 2012).

We determined that these changes will not increase the economic burden on any operator or increase the scope of the AD.

Costs of Compliance

We estimate that this AD affects 1,016 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Visual inspection	2 work-hours × $85 per hour = $170	Not applicable	$170	$172,720

We have no way of determining how much damage may be found on each airplane during the required inspection. The scope of damage on the exhaust system could vary from airplane to airplane due to the manner and environments airplane may operate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing airworthiness directive (AD) AD 82–16–05 R1, Amendment 39–5278 (51 FR 11707, April 7, 1986) and adding the following new AD:

2013–10–04 Piper Aircraft, Ltd.: Amendment 39–17457; Docket No. FAA–2012–0983; Directorate Identifier 2012–CE–001–AD.

(a) Effective Date

This AD is effective July 17, 2013.

(b) Affected ADs

This AD supersedes AD 82–16–05 R1, Amendment 39–5278 (51 FR 11707, April 7, 1986).

(c) Applicability

This AD applies to turbocharged Piper Aircraft, Inc. Models PA–31, PA–31–325, and PA–31–350 airplanes, all serial numbers, certificated in any category.

(d) Subject

Joint Aircraft System Component (JASC)/ Air Transport Association (ATA) of America Code 78, Engine Exhaust.

(e) Unsafe Condition

This AD was prompted by the forced landings of aircraft due to exhaust system failures between recurring detailed inspections. We are issuing this AD to prevent the possibility of an in-flight powerplant fire due to an exhaust system failure.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Visual Inspection

(1) Within the next 60 hours time-in-service (TIS) after July 17, 2013 (the effective date of this AD) or within the next 6 months after July 17, 2013 (the effective date of this AD), whichever occurs first, and repetitively thereafter at intervals not to exceed 60 hours TIS or 6 months, whichever occurs first, perform the inspections listed in table 1 of paragraph (g) of this AD upon the parts listed in the same table.

Note 1 to paragraph (g)(1) of this AD: Inspection procedure references can be found in Section 2, Visual Inspection, Chapter 5, Nondestructive Inspection (NDI), FAA Advisory Circular 43.13–1 B, Change 1, dated September 27, 2001, Acceptable Methods, Techniques, And Practices—Aircraft Inspection and Repair (*http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/99C827DB9BAAC81B86256B4500596C4E?OpenDocument&Highlight=ac43.13-1b).*

(2) Aircraft equipped with Supplemental Type Certificate (STC) SA240CH heat exchanger will not have all of the parts referenced in table 1 of paragraph (g). (Information on STC SA240CH may be found at *http://rgl.faa.gov/Regulatory_and_Guidance_Library/rgstc.nsf/0/30C512E870BE421D86257297005B6822?OpenDocument&Highlight=sa240ch.*) The heat exchanger replaces some of those parts; therefore, this AD requires the visual inspection on only the remaining parts listed in table 1 of paragraph (g) of this AD after installation of STC SA240CH. Airplanes modified in accordance with STC SA240CH will not require an Alternative Method of Compliance if the corrective actions in this AD are complied with.

TABLE 1 OF PARAGRAPH (g)—RECURRING 60-HOUR INSPECTIONS FOR LYCOMING AND PIPER EXHAUST SYSTEM PARTS

Product/part nomenclature	Make	Model/part number			Inspect with light and mirror or other method capable of achieving an equivalent visual resolution:
Airplane	Piper	PA–31	PA–31–325	PA–31–350	
Engine	Lycoming	TIO–540–A1A, –A1B, –A2A, –A2B and –A2C (standard cylinder flange; aka, narrow deck).	TIO–540–A2C (wide cylinder flange; aka, wide deck) and –F2BD, and LTIO–540–F2BD.	TIO–540–J2B and –J2BD and LTIO–540–J2B and –J2BD.	
Pipe, exhaust, right intermediate.	Lycoming	LW–15850	LW–15850	LW–15849	bulges, cracks and exhaust leak stains.
Pipe, exhaust, right rear, intermediate.	Lycoming	LW–16792	LW–16792	LW–16621	bulges, cracks and exhaust leak stains.
Pipe, exhaust, right rear.	Lycoming	LW–16793	LW–16793	LW–16620	bulges, cracks and exhaust leak stains.
Pipe, exhaust, left, intermediate.	Lycoming	LW–15849	LW–15849	LW–15849	bulges, cracks and exhaust leak stains.
Pipe, exhaust, left rear, intermediate.	Lycoming	LW–16789	LW–16789	LW–16696	bulges, cracks and exhaust leak stains.
Pipe, exhaust, left rear	Lycoming	LW–16790	LW–16790	LW–16697	bulges, cracks and exhaust leak stains.
Tail pipe assembly, bottom.	Piper	40310–09	40310–09	40310–09	bulges, cracks and exhaust leak stains.
Tail pipe assembly, top.	Piper	40310–08 or 40310–10.	40310–08 or 40310–10.	40319–10	bulges, cracks and exhaust leak stains.
v-band coupling	Lycoming	LW–12093–5	LW–12093–5	LW12093–5	cracks and exhaust leak stains.
v-band coupling	Piper	555–511 or 557–584	555–511 or 557–584	555–366 or 557–369	cracks and exhaust leak stains.

(h) Corrective Actions

(1) If any damage is found as a result of the inspections required in paragraph (g) of this AD, before further flight, do the following corrective actions:

(i) Replace v-band couplings exhibiting cracks and/or exhaust leak stains with airworthy and replacement v-band couplings following the applicable instructions contained in Piper Aircraft Corporation Service Bulletin No. 644E, dated May 9, 2012, and/or Lycoming Service Instruction No. 1238B, dated January 6, 2010.

(ii) Replace exhaust system parts exhibiting bulges, cracks and/or exhaust leak stains with airworthy parts in accordance with Lycoming Service Information 1320, dated March 7, 1975, and Lycoming Service Information 1391, dated October 5, 1979, as applicable.

Note 2 to paragraph (h) of this AD: During installation, we recommend not opening the v-band coupling more than the MINIMUM diameter necessary to clear coupled flanges. It is recommended to replace any locknuts and/or mating couplings with airworthy parts when locknuts do not exhibit a prevailing torque when installed.

(i) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in the Related Information section of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(j) Related Information

(1) For more information about this AD, contact Gary Wechsler, Aerospace Engineer, Atlanta ACO, FAA, 1701 Columbia Avenue, College Park, Georgia 30337; telephone: (404) 474–5575; fax: (404) 474–5606; email: *gary.wechsler@faa.gov.*

(2) Section 2, Visual Inspection, Chapter 5, Nondestructive Inspection (NDI), FAA Advisory Circular 43.13–1 B, Change 1, dated September 27, 2001, Acceptable Methods, Techniques, And Practices—Aircraft Inspection and Repair may be found at *http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgAdvisoryCircular.nsf/0/99C827DB9BAAC81B86256B4500596C4E?OpenDocument&Highlight=ac43.13-1b.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise:

(i) Piper Aircraft Corporation Service Bulletin No. 644E, dated May 9, 2012;

(ii) Lycoming Service Instruction No. 1238B, dated January 6, 2010;

(iii) Lycoming Service Instruction 1320, dated March 7, 1975; and

(iv) Lycoming Service Instruction 1391, dated October 5, 1979.

(3) For obtaining service information identified in this AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, Florida 32960; telephone: (772) 567–4361; fax: (772) 978–6573; Internet: *www.piper.com/home/pages/Publications.cfm.*

(4) You may view this service information at FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Kansas City, Missouri, on May 16, 2013.

Earl Lawrence,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2013–13666 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 73

[Docket No. FDA–2012–C–0224]

Listing of Color Additives Exempt From Certification; Mica-Based Pearlescent Pigments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is amending the color additive regulations to provide for the safe use of mica-based pearlescent pigments prepared from titanium dioxide and mica as color additives in distilled spirits containing not less than 18 percent and not more than 23 percent alcohol by volume but not including distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis. This action is in response to a petition filed by E. & J. Gallo Winery.

DATES: This rule is effective July 15, 2013. See section VIII for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing by July 12, 2013.

ADDRESSES: You may submit either electronic or written objections and requests for a hearing identified by Docket No. FDA–2012–C–0224, by any of the following methods:

Electronic Submissions

Submit electronic objections in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written objections in the following ways:

• *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–C–0224 for this rulemaking. All objections received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting objections, see the ''Objections'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or objections received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Raphael A. Davy, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1272.

SUPPLEMENTARY INFORMATION:

I. Background

In a document published in the **Federal Register** of March 22, 2012 (77 FR 16784), FDA announced that a color additive petition (CAP 2C0294) had been filed by E. & J. Gallo Winery, c/o Keller and Heckman LLP, One Embarcadero Center, Suite 2110, San Francisco, CA 94111. The petition proposed to amend the color additive regulations in § 73.350 (21 CFR 73.350) *Mica-based pearlescent pigments,* to provide for the safe use of mica-based pearlescent pigments prepared from titanium dioxide and mica in distilled spirits containing not less than 18 percent and not more than 23 percent alcohol by volume but not including distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis. The maximum use level of the pigments proposed by the petitioner is 0.07 percent by weight in the distilled spirits. Mica-based pearlescent pigments prepared from titanium dioxide and mica are currently permitted under § 73.350 for use as color additives in amounts up to 1.25 percent by weight in cereals, confections and frostings, gelatin deserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum. Mica-based pearlescent pigments prepared from titanium dioxide, iron oxide, and mica are permitted for use as color additives in ingested drugs under § 73.1350 (21 CFR 73.1350) and in contact lenses under 21 CFR 73.3128.

II. Safety Evaluation

A. Determination of Safety

Under section 721(b)(4) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379e(b)(4)), a color additive cannot be listed for a particular use unless a fair evaluation of the data and information available to FDA establishes that the color additive is safe for that use. FDA's color additive regulations in 21 CFR 70.3(i) define ''safe'' as the existence of ''convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.''

To establish with reasonable certainty that a color additive intended for use in food is safe under its intended conditions of use, we consider the projected human dietary intake of the additive, toxicological data on the additive, and other relevant information available to us. We compare an individual's estimated daily intake (EDI) of the additive from all sources for both the mean and high-intake consumer to an acceptable daily intake (ADI) level established by toxicological data. The EDI is determined by projections based on the amount of the additive proposed for use in particular foods and on data regarding the amount consumed from all sources of the additive.

B. Safety of the Petitioned Use of the Color Additive

During our review of the safety of the petitioned use of mica-based pearlescent pigments in distilled spirits, we considered the exposure to the color additive from both its petitioned use and from the uses for which it is currently permitted in food and ingested drugs under §§ 73.350 and 73.1350, respectively. In estimating the cumulative exposure to these pigments, we also considered the exposure to these pigments from their uses in contact lenses and determined that such exposure would be negligible.

For those consuming mica-based pearlescent pigments from the petitioned use in distilled spirits, we have estimated the exposure to mica-based pearlescent pigments at the mean and at the 90th percentile to be 0.12 grams/person/day (g/p/d) and 0.25 g/p/d, respectively, for persons aged 2 years or more (Ref. 1).

Previously, in the issuance of § 73.350 we calculated a cumulative EDI (CEDI) for the use of mica-based pearlescent pigments in food (§ 73.350) and ingested drugs (§ 73.1350) (71 FR 31927, June 2, 2006). For those exposed to mica-based pearlescent pigments from their use in food and ingested drugs, the CEDI was estimated to be 0.24 g/p/d and 0.48 g/p/d at the mean and at the 90th percentile, respectively, for persons aged 2 years or more, and to be 0.26 g/p/d and 0.52 g/p/d at the mean and at the 90th percentile, respectively, for the subgroup of children aged 2 to 5 years (71 FR 31927). This exposure estimate used food consumption data from the 1994 to 1996 and 1998 Continuing Survey of Food Intakes by Individuals

(CSFII) survey, which was integrated into the National Health and Nutrition Examination Survey (NHANES) in 2002.

In our current safety assessment, we updated the previous exposure to mica-based pearlescent pigments from all regulated uses in foods using the latest publicly available NHANES food consumption data (2003 to 2008). In estimating the exposure from the use of mica-based pearlescent pigments in ingested drugs, we relied on the estimates used in the issuance of § 73.350 (71 FR 31927). The current CEDI of mica-based pearlescent pigments from the petitioned use in distilled spirits and its regulated uses in food and ingested drugs is 0.26 g/p/d at the mean and 0.52 g/p/d at the 90th percentile for persons aged 2 years or more, and also for the subgroup of children aged 2 to 5 years (Ref. 1). The current CEDIs of mica-based pearlescent pigments are not significantly different from the previous CEDIs, as the percent of the population consuming distilled spirits from the petitioned use is low compared to the percent of the population consuming foods and ingested drugs formulated with mica-based pearlescent pigments. Further, our estimate assumes no contribution from the petitioned use of mica-based pearlescent pigments to the CEDI for the subgroup of children aged 2 to 5 years because they do not typically consume distilled spirits (Ref. 1).

In our previous safety evaluation of mica-based pearlescent pigments in food, which the petitioner referenced, we established an ADI level for mica-based pearlescent pigments to be 1.8 g/p/d based on a 2-year rat carcinogenicity bioassay that tested a 1:1 blend of mica and titanium dioxide (71 FR 31927 at 31928). Since the CEDI is less than the ADI, we conclude that the proposed expanded use of mica-based pearlescent pigments as color additives at a level of up to 0.07 percent by weight in distilled spirits is safe (Ref. 2).

III. Conclusion

Based on the data and information in the petition and other relevant material, FDA concludes that the petitioned use of mica-based pearlescent pigments prepared from titanium dioxide and mica as a color additive at a level of up to 0.07 percent by weight in distilled spirits containing not less than 18 percent and not more than 23 percent alcohol by volume but not including distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis is safe. We further conclude that the additive will achieve its intended technical effect and is suitable for use in coloring food. Therefore, we conclude that the color additive regulations should be amended as set forth in this document. In addition, based upon the factors listed in 21 CFR 71.20(b), we conclude that certification of titanium dioxide-coated mica-based pearlescent pigments is not necessary for the protection of the public health.

IV. Public Availability of Documents

In accordance with § 71.15 (21 CFR 71.15), the petition and the documents that we considered and relied upon in reaching our decision to approve the petition will be made available for public disclosure (see **FOR FURTHER INFORMATION CONTACT**). As provided in § 71.15, we will delete from the documents any materials that are not available for public disclosure.

V. Environmental Impact

We have previously considered the environmental effects of this rule as announced in the notice of filing for CAP 2C0294 (77 FR 16784, March 22, 2012). No new information or comments have been received that would affect our previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

VI. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VII. Section 301(ll) of the FD&C Act

FDA's review of this petition was limited to section 721 of the FD&C Act. This final rule is not a statement regarding compliance with other sections of the FD&C Act. For example, the Food and Drug Administration Amendments Act of 2007, which was signed into law on September 27, 2007, amended the FD&C Act to, among other things, add section 301(ll) of the FD&C Act (21 U.S.C. 331(ll)). Section 301(ll) of the FD&C Act prohibits the introduction or delivery for introduction into interstate commerce of any food that contains a drug approved under section 505 of the FD&C Act (21 U.S.C. 355), a biological product licensed under section 351 of the Public Health Service Act (42 U.S.C. 262), or a drug or biological product for which substantial clinical investigations have been instituted and their existence has been made public, unless one of the exemptions in section 301(ll)(1)–(4) of the FD&C Act applies. In our review of this petition, we did not consider whether section 301(ll) of the FD&C Act or any of its exemptions apply to food containing this color additive. Accordingly, this final rule should not be construed to be a statement that a food containing this color additive, if introduced or delivered for introduction into interstate commerce, would not violate section 301(ll) of the FD&C Act. Furthermore, this language is included in all color additive final rules that pertain to food and therefore should not be construed to be a statement of the likelihood that section 301(ll) of the FD&C Act applies.

VIII. Objections

This rule is effective as shown in the **DATES** section of this document; except as to any provisions that may be stayed by the filing of proper objections. Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (see **ADDRESSES**) either electronic or written objections regarding this document. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. It is only necessary to send one set of documents. Identify documents with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.* FDA will publish notice of the objections that the Agency has received or lack thereof in the **Federal Register**.

IX. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.*

1. Memorandum from Hyoung S. Lee, Division of Petition Review, Chemistry Review Team, to Raphael Davy, Division of Petition Review, Regulatory Group I, May 30, 2012.

2. Memorandum from Tina W. Walker, Division of Petition Review, Toxicology Team, to Raphael Davy, Division of Petition Review, Regulatory Group I, October 3, 2012.

List of Subjects in 21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 73 is amended as follows:

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 1. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

■ 2. Section 73.350 is amended by revising paragraph (c)(1) to read as follows:

§ 73.350 Mica-based pearlescent pigments.

* * * * *

(c) * * *

(1) The substance listed in paragraph (a) of this section may be safely used as a color additive in food as follows:

(i) In amounts up to 1.25 percent, by weight, in the following foods: Cereals, confections and frostings, gelatin desserts, hard and soft candies (including lozenges), nutritional supplement tablets and gelatin capsules, and chewing gum.

(ii) In amounts up to 0.07 percent, by weight, in distilled spirits containing not less than 18 percent and not more than 23 percent alcohol by volume but not including distilled spirits mixtures containing more than 5 percent wine on a proof gallon basis.

* * * * *

Dated: June 6, 2013.

Susan M. Bernard,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2013–13857 Filed 6–11–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 316

[Docket No. FDA–2011–N–0583]

RIN 0910–AG72

Orphan Drug Regulations

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing final regulations amending the 1992 Orphan Drug Regulations issued to implement the Orphan Drug Act. These amendments are intended to clarify regulatory provisions and make minor improvements to address issues that have arisen since those regulations were issued.

DATES: This rule is effective August 12, 2013.

FOR FURTHER INFORMATION CONTACT: Erica K. McNeilly, Office of Orphan Products Development, Food and Drug Administration, Bldg. 32, rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8660.

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I. Background

In the **Federal Register** of October 19, 2011 (76 FR 64868), FDA issued a proposed rule to amend the Orphan Drug Regulations (part 316 (21 CFR part 316)), to clarify certain regulatory language and propose areas of minor improvement regarding orphan-drug designation and orphan-drug exclusivity. The proposed rule addressed the following aspects of the Orphan Drug Regulations: (1) Demonstration of an appropriate ''orphan subset'' of persons with a particular disease or condition that otherwise affects 200,000 or more persons in the United States (''non-rare disease or condition''), for the purpose of designating a drug for use in that subset; (2) eligibility for designation of a drug that is otherwise the same drug for the same use as a previously approved drug; (3) eligibility for multiple orphan-drug exclusive approvals when a drug is designated for use in a rare disease or condition,[1] but is then separately approved for different indication(s) or use(s) within that particular rare disease or condition; (4) requirement for demonstrating clinical superiority for the purpose of orphan-drug exclusive approval when the drug is otherwise the same as a previously approved drug for the same use or indication; (5) requirement for submitting the name of the drug in a designation request; (6) required drug description and scientific rationale in a designation request; (7) required information in a designation request relating to the sponsor's interest in the drug; (8) timing of a request for orphan-drug designation; (9) responding to a deficiency letter from FDA on an orphan-drug designation request; (10) FDA publication of information regarding orphan-drug designations; (11) FDA recognition of orphan-drug exclusive approval; (12) miscellaneous terminology changes; and (13) an address change.

FDA received comments on the proposed rule from 14 entities, mainly from companies and trade associations of companies that are marketing or hope to market orphan drugs. On the whole, the comments were strongly supportive of the orphan drug program and recognized the need for clarity in FDA requirements, though many comments raised objections to and questions about certain aspects of the proposed rule.

[1] Section 526(a) of the Federal Food, Drug and Cosmetic Act (FD&C Act) defines a ''rare disease or condition'' to include any disease or condition that affects fewer than 200,000 persons in the United States.

II. Overview of the Final Rule

This rule largely finalizes the revisions as proposed, with several changes for clarity and accuracy and one substantive change involving publication when a drug no longer has orphan-drug designation. The main changes from the proposed rule are as follows:

- Adding a definition of ''orphan subset'' to § 316.3(b)(13), using a definition that is consistent with the explanation of orphan subset in the proposed rule.
- Clarifying the existing regulation in accordance with FDA's long-standing practice that a designated drug is eligible for orphan exclusive approval only if the same drug has not already been approved for the same use or indication,[2] by adding clarifying language to §§ 316.3(b)(12), 316.31(a), and 316.34(a).
- Removing the language in the proposed rule that, to demonstrate clinical superiority in terms of ''major contribution to patient care'' (§ 316.3(b)(3)(iii)), the drug must provide safety and effectiveness ''comparable to the approved drug.'' This language incorrectly implied that FDA would require direct proof of comparability to the already approved drug to demonstrate that a drug provides a major contribution to patient care (e.g., through non-inferiority trials).
- Adding an email address to the list of contact information required in requests for designation (§ 316.20(b)(2)), and making a related edit to the provision addressing the contact information required for permanent-resident agents (§ 316.22).
- Clarifying that a designation request need include only ''relevant'' in vitro laboratory data, as well as data from ''clinical experience'' with the drug in the rare disease or condition (§ 316.20(b)(4)). The proposal had omitted the qualifier ''relevant'' before in vitro laboratory data and had limited the clinical data to data from ''clinical investigations.'' FDA may in some cases consider other clinical data, such as well-documented case histories or significant human experience with the drug, as appropriate.
- Clarifying that, whenever FDA considers a designation request voluntarily withdrawn, FDA will notify the sponsor in writing (§ 316.24(a)). The proposal had erroneously implied that FDA would so notify the sponsor in writing only if the request was considered voluntarily withdrawn because FDA had denied a sponsor's request for an extension of time to respond to a deficiency letter, and not also if the sponsor had simply failed to respond, or request an extension of time to respond, within 1 year of issuance of the deficiency letter.
- Clarifying that, in addition to the reasons already expressly specified in § 316.25, FDA can refuse to grant a designation request if the request is otherwise ineligible for designation under part 316 (§ 316.25(b)). This revision merely codifies FDA's longstanding interpretation.
- Stating that FDA's publicly available posting of designated drugs will include whether a drug is no longer designated if the drug loses designation after the effective date of this final rule (§ 316.28). This information used to be deducible from FDA's publication of hard copy quarterly lists of designated drugs: Drugs no longer designated would appear on earlier hard copy lists but not on later ones. Once FDA switched to Internet publication, this information was no longer deducible owing to database limitations at the time. FDA is also making a technical correction to § 316.28 to reflect that FDA no longer places an annual list of designated drugs on file at FDA's Division of Dockets Management.
- Making explicit an option that has always existed for sponsors—that sponsors may voluntarily withdraw a designation request, or an actual designation, at any time by submitting a written request to FDA (§ 316.24(d)).
- Clarifying that the scope of orphan exclusive approval is limited to the indication(s) or use(s) for which the designated drug is approved (§ 316.31(a) and 316.31(b)). The proposal had used the term ''subset'' instead of ''indication(s) or use(s)'' (i.e., where a drug is approved for only a subset of patients with the rare disease or condition for which the drug is designated), which readers may have confused with the regulatory concept of ''orphan subset'' at § 316.20(b)(6). A reference to ''orphan subset'' was not intended at § 316.31. Orphan subset is a regulatory concept relevant to eligibility for orphan-drug designation, whereas this regulation at § 316.31 concerns the scope of orphan exclusive approval.
- Clarifying that a designated drug that is otherwise the same as a previously approved drug receives 7-years market exclusivity (''orphan-drug exclusivity'') upon approval only if the sponsor of the second-in-time drug demonstrates upon approval that its drug is clinically superior to the previously approved drug (§ 316.34(c)). This language corrects two possible misinterpretations of the proposed rule, by clarifying that: (1) Sponsors may have to demonstrate clinical superiority to obtain orphan-drug exclusivity even if they did not have to submit a plausible hypothesis of clinical superiority to obtain designation (e.g., if the same drug is approved for the same use after the designation but before the approval of the sponsor's drug); and (2) FDA will recognize orphan-drug exclusivity as long as clinical superiority to the previously approved drug is demonstrated, regardless of whether the sponsor substantiates the particular hypothesis of clinical superiority upon which designation was based (e.g., the drug may in fact be safer for a different reason than that hypothesized at the designation stage, or it may be demonstrated to be more effective instead of safer).
- Updating the FDA address listed at §§ 316.22 and 316.50 (in addition to doing so at § 316.4, as proposed) and adding an online address for the Orange Book at § 316.34(b).

This rule is intended to assist sponsors who are seeking and who have obtained orphan-drug designation of their drugs, as well as FDA in administering the orphan drug program. As described in the proposed rule (76 FR 64868), FDA believes these revisions will clarify, streamline, and improve the orphan-drug designation process. These amendments are fully consistent with the Orphan Drug Act (Pub. L. 97–414) and continue to provide incentives for the development of potentially promising orphan drugs that may not otherwise be developed and approved, including drugs that are potentially safer or more effective than already approved drugs.

III. Summary of and Response to Comments

FDA received comments on the proposed rule from 14 entities, mainly from companies and trade associations of companies that are marketing or hope to market orphan drugs. On the whole, the comments were strongly supportive of the orphan drug program and recognized the need for clarity in FDA requirements. Many comments also raised objections to and questions about certain aspects of the proposed rule, particularly the deletion of the phrase ''medically plausible'' from § 316.20 and clarification of the requirement for demonstrating clinical superiority to obtain orphan-drug exclusive approval.

Below, FDA responds to the comments in the order in which the sections were presented in the proposed rule. To make it easier to identify comments and our responses, the word

[2] Elsewhere in this preamble, we use the phrase ''same use'' as short-hand for ''same use or indication.''

''Comment,'' in parentheses, appears before the comment's description and the word ''Response,'' in parentheses, appears before our response. We have numbered each comment to help distinguish between different comments. Similar comments are grouped together under the same number. The number assigned to each comment is purely for organizational purposes and does not signify the comment's value, importance, or the order in which it was received.

A. Demonstration of an ''Orphan Subset'' of a Non-Rare Disease or Condition [3]

(Comment 1) Four comments objected to the proposal to delete ''medically plausible'' from the regulatory provision describing an orphan subset at § 316.20(b)(6), on the ground that this proposal would appear to narrow eligibility for orphan-drug designation. These comments asked FDA to retain ''medically plausible'' in the regulation.

(Response) FDA carefully considered whether to retain ''medically plausible'' in the regulatory provision describing an orphan subset at § 316.20(b)(6). Because of the confusion created by the term ''medically plausible,'' FDA decided to finalize the description of orphan subset as proposed. This confusion was manifest in the very comments objecting to the proposal and asking that the term ''medically plausible'' be retained.

As explained in the proposed rule (76 FR 64868 at 64869 to 64870), the term ''medically plausible'' has been misinterpreted by sponsors to mean any medically recognizable or clinically distinguishable subset of persons with a particular disease or condition—a misunderstanding reflected in some of the comments described previously. This misinterpretation of ''medically plausible,'' if accepted by FDA, could result in artificially narrow subsets for the purpose of orphan-drug designation. It could permit a non-rare disease or condition to be artificially subdivided into smaller groups for establishing subsets that are under the prevalence limit for designation. FDA does not believe that such an approach would serve the intent of the Orphan Drug Act, as explained in the proposed rule (76 FR 64868 at 64869 to 64870). Use of such artificial orphan populations to obtain orphan-drug designation and its related benefits would divert resources away from research and development of drugs for true orphan diseases and conditions. Further, it would encourage sponsors to study and seek approval for use of a drug in the narrowest possible artificial patient groupings within a disease or condition in order to avail themselves of the orphan-drug incentives, including tax benefits and orphan-drug exclusive approval, when other patients with the disease or condition would also benefit from use of the drug. Under this scenario, sponsors could even potentially ''game'' approvals by seeking successive narrow approvals of a drug to avail themselves of orphan-drug benefits when the overall approved use is not an orphan use. These outcomes would be inconsistent with the Orphan Drug Act.

By removing ''medically plausible'' from § 316.120(b)(6) and instead inserting a description of what orphan subset means, FDA aims to dispel the confusion created by the term ''medically plausible.'' This description is consistent with how FDA has long interpreted ''medically plausible'' in the context of orphan subsets. It is intended to make clear to sponsors that an orphan subset is a regulatory concept specific to the Orphan Drug regulations, and that it does not simply mean any medically recognizable or clinically distinguishable subset of persons with a particular disease or condition (as the term ''medically plausible'' in this context may have been erroneously interpreted to imply). Under FDA's longstanding approach, eligibility for orphan subsets rests on whether use of the drug in a subset of persons with a non-rare disease or condition may be appropriate but use of the drug outside of that subset (in the remaining persons with the non-rare disease or condition) would be inappropriate owing to some property(ies) of the drug, for example, drug toxicity, mechanism of action, or previous clinical experience with the drug. This is the same requirement as the requirement that FDA long employed for identifying ''medically plausible'' subsets for the purpose of orphan-drug designation. To be clear, FDA has never interpreted ''medically plausible'' to mean what these comments appear to claim it means. Thus, contrary to what these comments suggest, replacing ''medically plausible'' with a description of orphan subset will not result in a narrowing of eligibility for orphan-drug designation.

Partly in response to the confusion expressed by these comments, FDA is making a slight edit to § 316.20(b)(6) to expressly incorporate the term ''orphan subset.'' In place of the opening clause, ''Where a drug is under development for only a subset of persons with a particular disease or condition that otherwise affects 200,000 or more people,'' FDA is inserting the following language: ''Where a sponsor requests orphan-drug designation for a drug for only a subset of persons with a particular disease or condition that otherwise affects 200,000 or more people ('orphan subset'), . . . '' This edit has two advantages: it incorporates an overt reference to ''orphan subset'' into the regulatory language, and it clarifies that sponsors can seek designation of a drug for an orphan subset before they begin developing that drug. FDA is also adding ''orphan subset'' to the definition section at § 316.3(b)(13), as follows: ''*Orphan subset of a non-rare disease or condition ('orphan subset')* means that use of the drug in a subset of persons with a non-rare disease or condition may be appropriate but use of the drug outside of that subset (in the remaining persons with the non-rare disease or condition) would be inappropriate owing to some property(ies) of the drug, for example, drug toxicity, mechanism of action, or previous clinical experience with the drug.''

Finally, we note that we are retaining the term ''medically plausible'' elsewhere in part 316 when describing whether the scientific rationale for use of the drug for the rare disease or condition is adequate (§ 316.25(a)(2)) and whether the hypothesis of clinical superiority, if required, is plausible (§ 316.25(a)(3)). Unlike in the orphan subset context, the term ''medically plausible'' has not caused confusion among sponsors in these contexts. FDA is therefore retaining the original ''medically plausible'' terminology at § 316.25(a).

(Comment 2) Many comments asked FDA to clarify what subsets may be appropriate for the purpose of orphan-drug designation.

(Response) FDA advises sponsors that an orphan subset cannot be considered without reference to the drug, specifically to the property or properties of the drug that preclude its use in the remaining persons with the non-rare disease or condition, outside of the orphan subset. FDA explained in the proposed rule (76 FR 64868 at 64869 to 64870) what factors may inform whether an appropriate orphan subset exists for the purpose of orphan-drug designation. In response to these comments, FDA is providing further explanation here.

Factors that may inform whether an appropriate orphan subset exists

[3] As in the proposed rule, in this final rule FDA is not changing the regulatory provisions allowing sponsors to obtain orphan-drug designation for a drug intended for a disease or condition affecting 200,000 or more people, or for a vaccine, diagnostic drug, or preventive drug to be administered to 200,000 or more people per year, if there is no reasonable expectation that research and drug development costs can be recovered by sales of the drug in the United States. (§§ 316.20(b)(8)(ii) and 316.21(c)).

include pharmacologic or biopharmaceutical properties of the drug and previous clinical experience with the drug. For example:

• Toxicity of the Drug: The toxicity profile of the drug may render it appropriate for use in only a subset of persons with a non-rare disease or condition. For example, patients with the disease or condition who can be treated with other, less toxic therapies may not be appropriate candidates for the drug; however, a subset of patients with the disease or condition who are refractory to, or intolerant of, other less toxic drugs may exist and may be the only appropriate candidates for treatment with the more toxic drug.

• Mechanism of Action of the Drug (e.g., antibody-specific or biomarker-based drug): The mechanism of action of a drug may limit use of a drug to only a subset of patients with a non-rare disease or condition. For example, use of a certain targeted therapy (e.g., antibody-specific or biomarker-based drug) may be appropriate in only a subset of patients with a non-rare disease or condition owing to its targeting mechanism (e.g., only in patients with the subtypes of tumors that possess the specific antigen targeted or only those patients with the specific biomarker targeted).

• Previous Clinical Experience With the Drug: Information on the drug's activity available from completed clinical trials or published in clinical literature may be used to establish an orphan subset. For example, if relevant data show that the drug has no significant activity in the remaining subset of patients with high grade tumors or with a certain biomarker, respectively, then patients with low grade tumors or without that biomarker may constitute an orphan subset within a given disease or condition.

Factors that may not inform whether an orphan subset exists were also addressed in the proposed rule (76 FR 64868 at 64869 to 64870). These factors may include, by way of example:

• Clinical Trial Eligibility: An orphan subset is not appropriate where the subset of interest is defined only by eligibility to enroll in a given clinical trial to support a specific indication for use of a drug, where other persons with the disease or condition may also be appropriate candidates for the drug. That is, patients with a given disease or condition who simply meet inclusion or exclusion criteria for a trial do not automatically qualify as an orphan subset absent some property(ies) of the drug that would render its use inappropriate in the remaining persons with the disease or condition.

• Sponsor's Plan to Study the Drug for a Select Indication: An orphan subset does not exist simply because the sponsor plans to study the drug for a select indication within a disease or condition absent some property(ies) of the drug that would render its use inappropriate in the remaining persons with the disease or condition.

• Particular Disease Grade or Stage: An orphan subset does not exist for a drug for use in a subset of persons with a particular pathohistologic grade or clinical stage of a specific malignancy absent some property(ies) of the drug that would render its use inappropriate in the remaining persons with the disease or condition.

• Price: An orphan subset does not exist simply because the high price of a drug may render it unlikely to be used in a broader population with the disease or condition. The sponsor must show that use of the drug in the remaining persons with the disease or condition would be scientifically or medically inappropriate, not simply unlikely because of price or other factors.

(Comment 3) Many of the comments expressed concern that, in order to establish an orphan subset, sponsors would have to prove a negative: That the drug would not potentially benefit other subsets of persons with the non-rare disease or condition. As one comment noted, ''There may be reason to encourage study of a treatment for a clinically distinct subgroup, even if that treatment could also be used to treat a different clinically distinct subgroup or even a larger group with the same disease.''

(Response) FDA understands the concern about ''proof of a negative,'' but advises sponsors that an orphan subset cannot be artificially narrow. As noted in response to comments 1 and 2, an orphan subset must be based on some property(ies) of the drug, such as toxicity or mechanism of action, that would render its use inappropriate in the remaining persons with the disease or condition. This showing is not necessarily ''proof of a negative,'' as these comments may suggest; it need not necessarily rise to the level of ''scientific proof'' as that term in commonly understood.

Some of the concerns expressed by these comments are best addressed through discussion of what constitutes a distinct ''disease or condition'' for the purpose of orphan-drug designation. A drug that shows promise in multiple, different rare diseases or conditions may be eligible for multiple designations, one for each disease or condition, because FDA considers the prevalence within each disease or condition. For example, the same drug may be eligible for three separate designations: One for the treatment of ovarian cancer, one for the treatment of multiple myeloma, and one for the treatment of Kaposi's sarcoma, even if the cumulative prevalence of all three diseases or conditions would exceed 200,000. As long as the prevalence of each disease or condition is under 200,000, no orphan subset need be shown. If, however, the drug is for a disease or condition that exceeds the prevalence limit of 200,000, then the sponsor would need to establish an orphan subset based on some property(ies) of the drug, as described previously in the responses to comments 1 and 2.

Whether a given medical condition constitutes a distinct ''disease or condition'' for the purpose of orphan-drug designation depends on a number of factors, assessed cumulatively, including: Pathogenesis of the disease or condition; course of the disease or condition; prognosis of the disease or condition; and resistance to treatment. These factors are analyzed in the context of the specific drug for which designation is requested. For example, based on a cumulative assessment of the previous factors, FDA currently considers pneumonia in cystic fibrosis patients to be a different ''disease or condition'' than community-acquired pneumonia when evaluating orphan-drug designation requests for products that treat respiratory infection. Thus, assuming the prevalence of pneumonia in cystic fibrosis patients in the United States is under 200,000, but the pool of all pneumonia cases exceeds 200,000, sponsors seeking orphan-drug designation for a drug for pneumonia in cystic fibrosis patients need not establish an orphan subset from the larger pool of all pneumonia patients. They need not, in other words, provide a rationale for why only cystic fibrosis patients with pneumonia (and not patients with community-acquired pneumonia) would be appropriate candidates for the drug. By contrast, FDA currently considers stage 1 breast cancer to be the same ''disease or condition'' as stage 4 breast cancer when evaluating orphan-drug designation requests for products that treat breast cancer. Because the prevalence of breast cancer currently exceeds 200,000, sponsors seeking orphan-drug designation for a breast cancer drug would need to demonstrate why only a subset of patients with breast cancer (e.g., patients with stage 4 breast cancer) would be appropriate candidates for the drug. FDA acknowledges that what is considered a

distinct ''disease or condition'' may change over time as scientific understanding evolves, which would affect prevalence determinations.

If FDA considers the disease or condition in question to be a distinct ''disease or condition'' for the purpose of orphan-drug designation, then drugs for that disease or condition may be eligible for orphan-drug designation even if they may potentially benefit other patient groups (e.g., drugs for pneumonia in cystic fibrosis patients may be eligible for designation even if they may potentially benefit patients with community-acquired pneumonia). Assuming prevalence of the relevant disease or condition is under 200,000, no orphan subset need be shown; sponsors would not need to justify limiting use of the drug to only that rare disease or condition. A drug could thus be eligible for multiple designations if it meets the applicable criteria for orphan-designation for multiple diseases or conditions, one disease or condition per designation.

(Comment 4) One comment noted that the European Medicines Agency (EMA) uses the term ''medically plausible'' in its orphan drug program, and advised FDA to consult with EMA before removing the term from FDA regulations.

(Response) FDA reminds sponsors that, although FDA is replacing the term ''medically plausible'' with a description of what constitutes an orphan subset, FDA is not changing its longstanding approach to identifying when appropriate subsets exist for the purpose of orphan-drug designation. FDA is aware that EMA uses the term ''medically plausible'' in evaluating whether medicinal products are eligible for orphan-drug designation in the European Union. FDA appreciates that harmonization with EMA, where feasible, benefits many stakeholders, and to that end has created with EMA a ''Common Application'' for orphan-drug designation. There are, however, differences in the statutory and regulatory criteria for, and regulatory benefits associated with, orphan-drug designation in the United States compared to the European Union. Absent a myriad of legislative changes, FDA and EMA cannot completely harmonize in their approaches to designation. FDA believes that any benefit to be gained by retaining the term ''medically plausible'' in its regulations purely because the EMA employs the term is outweighed by the confusion this term has engendered among sponsors seeking designation from FDA.

(Comment 5) Two comments agreed with the proposal to replace ''medically plausible'' with a description of orphan subset. One of these comments requested the following two clarifications from FDA: One, that orphan subsets can exist regardless of whether the drug may be used or investigated in other subsets of persons with the non-rare disease or condition, as long as there is a reasonable scientific or medical basis for use of the drug in the subset of interest; and two, that orphan subsets can be based on biomarkers and other facets of ''personalized medicine'' (e.g., antibody-specific treatments).

(Response) The responses to comments 1 to 3 also address these comments. Consistent with FDA's longstanding approach, eligibility for orphan subsets rests on whether some property(ies) of the drug render its use inappropriate in the remaining persons with the disease or condition, outside of the subset of interest. FDA disagrees that an orphan subset can exist whenever there is a basis for using the drug in the subset of interest, regardless of whether the drug can also be used in the remaining persons with the disease or condition. FDA does, however, recognize that orphan subsets may be predicated on biomarker-based and other targeted treatments as a principle for limiting the use of a drug to only a subset of patients with a non-rare disease or condition (e.g., the subset with the specific biomarker targeted).

B. Eligibility for Orphan-Drug Designation of a Drug That Was Previously Approved for the Same Use or Indication

(Comment 6) Four comments were opposed to the proposal to delete the word ''orphan'' from the phrase ''approved orphan drug'' in §§ 316.3(b)(3), 316.20(a) and (b)(5), and the proposal to revise § 316.25(a)(3) to read ''already approved drug for the same disease or condition'' (in place of ''[a drug] that already has orphan-drug exclusive approval for the same disease or condition''), on the ground that FDA should grant designation more liberally by never requiring a plausible hypothesis of clinical superiority at the designation stage, even if the drug is otherwise the same as a previously approved drug (whether or not such previously approved drug has orphan exclusive approval). These comments interpret section 526 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bb) to mandate orphan-drug designation of any drug for a rare disease or condition, even those that are the same drug as a previously approved drug, regardless of clinical superiority, as long as the designation request for the drug is submitted before submission of the marketing application. At the same time, these comments acknowledge that, in order for the drug to receive and/or break orphan exclusivity under section 527 of the FD&C Act (21 U.S.C. 360cc), clinical superiority would need to be demonstrated upon approval if the drug is otherwise the same as a previously approved drug for the same use or indication.

According to these comments, more liberal granting of orphan-drug designation without changing orphan-drug exclusivity requirements would further the intent of the Orphan Drug Act, by fostering development of rare disease treatments without undercutting the exclusivity incentive/protection. Specifically, more liberal orphan-drug designation—even if orphan-drug exclusivity is not even theoretically available—would expand the universe of rare disease treatments eligible for the benefits (other than exclusivity) associated with designation under the Orphan Drug Act: particularly, Federal tax credits for the cost of conducting human clinical testing and exemption from application user fees.[4] These comments noted that the benefits associated with designation have expanded since passage of the Patient Protection and Affordable Care Act (ACA) in 2010 (Pub. L. 111–148), to include exemption from the annual pharmaceutical fee (excise tax) levied by ACA and exclusion from the 340B Drug Discount Program. According to these comments, Congress used orphan-drug designation as a ''proxy'' for protection of rare disease treatments in the ACA but without necessarily realizing that not all rare disease treatments are eligible for orphan-drug designation.

Two of these comments identify plasma protein therapies, in particular, as deprived of the benefits related to orphan-drug designation. Macromolecules are considered to be the ''same drug'' under the Orphan Drug regulations if they have the same principal molecular structure, despite some differences in structural features. If the ''same drug'' has already been approved for the same use, designation requires a plausible hypothesis of clinical superiority. As one of these comments explained, ''This [framework] affects the plasma protein therapeutics industry significantly because various drugs within each therapeutic class of

[4] This exemption from application user fees was enacted as part of the Prescription Drug User Fee Act of 1992, since reauthorized.

products are considered to have the same principal molecular structures and would not be considered different under the regulations without a showing of clinical superiority, despite the fact that each therapy is a unique, non-interchangeable biological product. This has important ramifications for the plasma industry because it has developed an exceptionally diverse selection of branded products within each therapeutic class, thus the industry's portfolio is predominantly composed of second-to-market products indicated to treat rare diseases, but not orphan designated.'' Because many plasma protein therapies lack orphan-drug designation, they are apparently ineligible for the legislative incentives for rare disease treatments enacted in other statutes, despite being indicated solely for rare diseases. According to comments, this outcome ''contradicts the overall purpose of the [Orphan Drug Act]'' by ''threatening the industry's capacity to continue to explore rare disease therapies.''

(Response) FDA appreciates this perspective from industry about the impact that obtaining—or not obtaining—orphan-drug designation under the Orphan Drug Act may have under other statutes unrelated to the Orphan Drug Act. Nevertheless, FDA continues to believe that the current framework is the best means for giving effect to the intent of the Orphan Drug Act, to provide incentives for sponsors to develop promising drugs for rare diseases and conditions that would not otherwise be developed and approved, including drugs that are potentially safer or more effective than already approved drugs. (See H.R. Rep. 97–840, Pt. 1, at 6 (1982); Orphan Drug Act, Pub. L. 97–414, § 1; see also *Genentech, Inc.* v. *Bowen,* 676 F. Supp. 301, 312 (D.D.C. 1987) (''The legislative history is replete with references to the fundamental need to provide treatment for *presently untreated patients.*'') (emphasis added).

FDA is, however, considering the feasibility of issuing a draft guidance document on what may constitute a plausible hypothesis of clinical superiority for certain categories of products, for example plasma-derived products, which may help address some of the concerns articulated previously.

(Comment 7) One comment opposed this proposal as an apparent ''expansion'' of the circumstances in which FDA would require a plausible hypothesis of clinical superiority, rather than a clarification of existing practice. This comment maintained that any clinical superiority requirement undermines the incentive structure of the Orphan Drug Act because clinical superiority can be difficult to prove.

(Response) As explained in the proposed rule (76 FR 64868 at 64870), FDA is not expanding the circumstances in which it will require a plausible hypothesis of clinical superiority for orphan-drug designation. It is merely clarifying its longstanding practice. In the absence of a clinical superiority hypothesis, the Agency does not interpret the Orphan Drug regulations to permit designation of a drug that is otherwise the same as a drug that is already approved for the same use, regardless of whether the previously approved drug obtained orphan-drug designation or was eligible for orphan-drug exclusivity. For a more detailed description of how FDA interprets its current regulations, see the response to comment 8. FDA believes this interpretation best reflects the intent of Orphan Drug Act, as explained in response to comment 6, by encouraging the development of potentially safer and more effective orphan drugs—rather than encouraging minor modifications to already approved drugs that confer no meaningful benefit to patients.

In response to the comment that clinical superiority can be difficult to prove, FDA advises sponsors that the clinical superiority requirements for orphan-drug designation and orphan-drug exclusivity are different: designation requires a plausible hypothesis of clinical superiority, exclusivity requires a demonstration of clinical superiority. As FDA has elsewhere explained (56 FR 3338 at 3341, January 29, 1991), this difference is intended to encourage the development of improved versions of existing drugs while protecting any applicable orphan-drug exclusivity. The former is achieved through liberally granting designation based on a plausible hypothesis of clinical superiority, allowing drugs to benefit from development incentives that flow from designation. The latter is achieved through reserving orphan-drug exclusivity for a subsequent drug—allowing the subsequent drug to be approved during the pendency of the already approved drug's exclusivity period (if any) and with its own period of orphan-drug exclusivity—provided that clinical superiority is demonstrated upon approval. This framework fulfills the main purpose of the Orphan Drug Act, to foster the development and innovation of orphan drug therapies, while taking care not to ''render [orphan-drug exclusivity] meaningless'' (57 FR 62077, December 29, 1992) e.g., by allowing any minor change to render a subsequent drug different from a previously approved drug and therefore not blocked by orphan-drug exclusivity. At the same time, if the sponsor of a subsequent drug that it is otherwise the same as a previously approved drug demonstrates clinical superiority to the previously approved drug, that subsequent drug may gain marketing approval and its own orphan-drug exclusivity, despite any existing exclusivity for the previously approved drug; it would also be eligible for exclusivity upon a clinical superiority showing where the previously approved drug's exclusivity period has run or never existed. FDA has implemented the Orphan Drug Act in this way to fulfill Congress' aim of incentivizing the development and innovation of orphan drugs and to ensure that orphan exclusivity has value to sponsors, while limiting its scope so that it does not ''preclude significant improvements in treating rare diseases'' (56 FR 3338).

(Comment 8) One comment objected to FDA's characterizing this proposal as ''clarifying current practice'' on the ground that FDA appears to be contradicting its current regulations. According to this comment, current § 316.25 lists the only reasons that FDA can ever decline to grant a designation request—and § 316.25 does not expressly list, as a reason, failure to include a plausible hypothesis of clinical superiority where the drug is the same as a previously approved drug that does not have orphan-drug exclusivity.

(Response) FDA disagrees that it is changing its current practice. As FDA explained in the proposed rule (76 FR 64868 at 64870), FDA has consistently interpreted the Orphan Drug regulations (in particular, § 316.20(a) and (b)(5)) to require that designation requests include a plausible hypothesis of clinical superiority if the drug is the same as an already approved drug, regardless of whether the already approved drug has orphan-drug exclusivity. If the same drug has already been approved for the same use, with or without orphan-drug exclusivity, designation without such a hypothesis would be inappropriate because it would be inconsistent with the primary purpose of the Orphan Drug Act, which is to provide incentives to develop promising orphan drugs that would not otherwise be developed and approved—not to encourage minor modifications to already approved drugs that confer no meaningful benefit to patients. *See* H.R. Rep. 97–840, Pt. 1, at 6 (1982); Orphan Drug Act, Public Law 97–414, § 1; see also *Genentech, Inc.* v. *Bowen,* 676 F. Supp. at 312 (''The legislative history is replete with references to the

fundamental need to provide treatment for *presently untreated patients.''*) (emphasis added).

FDA has never interpreted § 316.25, in particular, as an exhaustive list of the reasons that FDA can decline to grant designation. Although § 316.25 lists some reasons for refusing designation, it does not reiterate all of the eligibility criteria for designation that are embodied elsewhere in the statute and in part 316. These eligibility criteria include that the designation request be submitted before submission of the marketing application, as is required by section 526(a) and § 316.23(a), and that the product be a drug, as is required by section 526(a) and § 316.20. Under FDA's longstanding interpretation, a request that failed to meet any of these eligibility criteria would be denied on this ground alone without resort to § 316.25. An additional reason for not granting designation that is not currently listed at § 316.25, but is reflected elsewhere in part 316 (§ 316.20(a) and (b)(5)), is if a request for a drug is the same as a previously approved drug fails to include a plausible hypothesis of clinical superiority where the previously approved drug does not have orphan-drug exclusivity. Consistent with the proposed rule, FDA is revising § 316.25 in this final rule to expressly include this reason in the enumerated list.

Similarly, FDA has never interpreted § 316.24 to require automatic designation if a product fails to meet eligibility criteria captured elsewhere in part 316 but not reiterated in § 316.25. If a request is not eligible for designation because, for example, it fails to include a plausible hypothesis of clinical superiority when the drug is the same as a previously approved drug, or because the designation request was submitted after the marketing application had been submitted, then the request would not even fall into the ambit of § 316.24 (''Granting orphan-drug designation'').

In response to this comment's assertion that § 316.25 on its face appears to be an exhaustive list of the reasons that FDA can refuse to grant designation (especially when read alongside § 316.24), FDA has decided to further amend § 316.25(b) to make clear that FDA will deny designation if the request is otherwise ineligible for designation under part 316.

(Comment 9) One comment questioned why the preamble to the proposed rule identified change in dosage form as an example of ''inappropriate 'evergreening' of exclusive approval periods'' (76 FR 64868 at 64870), when some new dosage forms may provide significant patient benefit.

(Response) FDA agrees with this comment. Some new dosage forms may be ''clinically superior'' to previously approved dosage forms of the same drug under § 316.3(b)(3) and thus eligible for their own 7-year period of orphan exclusive approval. For example, a change in delivery system from intravenous (IV) to oral may, in some cases and for some drugs, constitute a ''major contribution to patient care'' under § 316.3(b)(3)(iii). As stated in the preamble to the 1992 final rule, Orphan Drug Regulations (57 FR 62077 at 62079), whether a change in delivery systems constitutes a major contribution to patient care ''can only be decided on a case-by-case basis, considering the nature of the disease or condition, the nature of the drug, the nature of the mode of administration, and other factors.'' For more on major contribution to patient care, see the responses to comments 14 and 15.

(Comment 10) One comment asked FDA to clarify that a sponsor that improves its own drug by demonstrating patient benefit is eligible for orphan-drug exclusivity for the improved drug, regardless of whether the sponsor's first drug received orphan-drug exclusivity.

(Response) FDA advises that if, upon approval, an orphan-designated drug is shown to be ''clinically superior'' under § 316.3(b)(3) to a previously approved drug, then it is eligible for orphan-drug exclusive approval regardless of the identity of the sponsor (e.g., even if the sponsor of both drugs is the same).

C. Eligibility for Multiple Orphan-Drug Exclusive Approvals

(Comment 11) One comment expressed confusion about the language in the preamble to the proposed rule (76 FR 64868 at 64870), ''If the sponsor who originally obtained orphan exclusive approval of the drug for only a subset of the orphan disease or condition for which the drug was designated subsequently obtains approval of the drug for one or more additional subsets of that orphan disease or condition, FDA will recognize orphan-drug exclusive approval, as appropriate, for those additional subsets from the date of such additional marketing approval(s). Before obtaining such additional marketing approval(s), the sponsor in this instance would not need to have obtained additional orphan designation for the additional subset(s) of the orphan disease or condition.'' The comment asked FDA to ensure that it would give orphan exclusive approval only to drugs that have been formally designated as orphan drugs, rather than giving orphan exclusive approval to drugs for indications for which they do not have orphan-drug designation.

(Response) FDA clarifies that the language excerpted previously from the preamble to the proposed rule was intended to convey the following circumstance: (1) A drug obtains orphan-drug designation for a rare disease or condition, (2) a drug obtains marketing approval (and orphan-drug exclusivity) for only select indications or uses within the rare disease or condition for which the drug was designated, (3) the sponsor subsequently obtains approval for additional (not previously approved) indications or uses of the drug within the same rare disease or condition for which the drug was designated, then (4) the drug may be eligible for a new period of orphan-drug exclusivity for those new approved indications or uses without the need to re-seek designation—because these new (not previously approved) indications or uses would fall within the scope of the original designation (i.e., because in this example the drug was designated for the rare disease or condition, not select indications or uses within that rare disease or condition). This example was not intended to suggest that FDA would grant orphan exclusive approval to a drug for a disease or condition for which the drug was not designated.

FDA reminds sponsors that, when FDA designates an orphan drug, it generally designates the drug for use by all persons with the rare disease or condition (or the orphan subset within a non-rare disease or condition) and expects that a sponsor will seek marketing approval of the drug for all persons with the rare disease or condition (or the orphan subset). FDA may, however, approve the drug for only select indications or uses within the rare disease or condition (or the orphan subset) because FDA can only approve a drug for the indications or uses for which there is adequate data and information in the marketing application to support approval. The scope of orphan-drug exclusivity is limited to the indication(s) or use(s) for which the drug is approved for marketing, even if the orphan-drug designation for the drug is broader. For example, a drug may be designated for use in ovarian cancer but approved for use in only stage 4 ovarian cancer, based on the data and information in the marketing application. As new data emerge, FDA may approve the drug for additional indications or uses within the rare disease or condition for which the drug is designated (e.g., stages 1, 2, and/or 3 of ovarian cancer). The advantage to the sponsor in this

hypothetical scenario is that, if the drug is later approved for additional indication(s) or use(s) within the rare disease or condition for which it is designated, the sponsor would not have to submit additional designation requests for the drug to cover these additional indication(s) or use(s)—because they would fall within the original designation. Additional orphan-drug exclusivity may attach upon approval of these new (not previously approved) indications or uses that are within the scope of the original designation.

In such a hypothetical scenario, a ''broad'' designation would not prevent other sponsors from obtaining designation and/or marketing approval for the same drug for the same rare disease or condition. If a drug is approved for only certain indications or uses within a rare disease or condition, a subsequent sponsor may obtain designation of the same drug for the remaining (not previously approved) indications or uses within the same rare disease or condition without having to provide a plausible hypothesis of clinical superiority over the already approved drug, provided that the prevalence of the entire disease or condition remains under 200,000. Assume, for example, that a drug is designated for use in ovarian cancer (all stages) but is approved for use in only stages 1 and 2 of ovarian cancer (''first drug''). A subsequent sponsor may seek designation of the same drug (''second drug'') for the remaining unapproved uses within ovarian cancer (i.e., stages 3 and/or 4) without having to provide a plausible hypothesis of clinical superiority over the first drug, although the prevalence determination would be based on ovarian cancer regardless of stage (unless an orphan subset were shown). Designation of the second drug for the uses already approved for the first drug (i.e., stages 1 and 2 of ovarian cancer) would require a plausible hypothesis of clinical superiority over the first already approved drug.

Prompted by the confusion expressed by comment 11, FDA has revised proposed § 316.31 for clarity. FDA has amended the final rule by replacing ''subset [of uses]'' (i.e., a drug is approved for only a subset of patients with the rare disease or condition for which the drug is designated) with ''select indication(s) or use(s),'' at § 316.31(a) and (b). The rule now uses the phrase ''indication(s) or use(s)'' in place of ''subset [of uses]'' because readers may have confused the latter with the regulatory concept of orphan subset at § 316.20(b)(6)—when a reference to ''orphan subset'' was not intended at § 316.31. Orphan subset is a regulatory concept relevant to eligibility for orphan-drug designation (see the responses to comments 1 to 3), whereas this regulation at § 316.31 concerns the scope of orphan-drug exclusive approval.

(Comment 12) One comment objected to FDA's practice, described previously in response to comment 11, of generally designating a drug for use by all persons with the rare disease or condition, even though the drug may eventually be approved for only certain indication(s) or use(s) within that rare disease or condition. Once the drug has already been approved for certain indication(s) or use(s) within the rare disease or condition (''first drug''), another sponsor seeking designation of the same drug (''second drug'') for use in the same rare disease or condition would need to provide a plausible hypothesis of clinical superiority over the first drug for the indication(s) or use(s) for which the first drug is approved. Alternatively, without providing such a hypothesis, the sponsor may seek designation of the second drug for only the unapproved indication(s) or use(s) within the rare disease or condition. The comment maintained that this designation practice could result in labeling confusion, Medicare reimbursement confusion, increased likelihood of medication errors, and product liability concerns, because end-users may have difficulty differentiating between the trade names and labeling of orphan-designated drugs that are approved for different uses within the same rare disease or condition.

(Response) FDA advises that the concerns expressed by this comment mainly concern the wording and scope of FDA-approved labeling, not orphan-drug designation. Requests for orphan-drug designation are submitted before the submission of a marketing application for a drug; whatever the scope of a drug's designation, its FDA-approved labeling will be determined by the data and information included in the marketing application. The scope of designation, in other words, does not determine the scope of FDA-approved labeling. As for the comment's concern that several drugs that are the same may be approved for different indications or uses within the same rare disease or condition, as the 4th Circuit Court of Appeals has held, orphan-drug exclusivity protects only the uses for which the drug is approved, not any and all uses of the drug. See *Sigma-Tau Pharms.* v. *Schwetz,* 288 F.3d 141, 145 (2002).

(Comment 13) Another comment asked FDA to clarify that, in the event a drug is designated for a given disease or condition, is approved (and granted orphan-drug exclusivity) for only certain indications or uses within that same disease or condition, and is subsequently approved for additional indications or uses within that same disease or condition, the drug is eligible for orphan-drug exclusivity without the need to show clinical superiority.

(Response) FDA agrees that, in the example provided previously, orphan-drug exclusivity may be obtained for the new indications or uses of the drug within the same disease or condition for which the drug was designated without the need to show clinical superiority, provided that the same drug has not already been approved for these new indications or uses. For more explanation, see the response to comment 11.

D. Demonstration of Clinical Superiority—Major Contribution to Patient Care

(Comment 14) Five comments asked FDA to clarify what ''comparable safety and effectiveness'' would mean in the context of major contribution to patient care under § 316.3(b)(3)(iii), and in particular what level of proof would be required (e.g., non-inferiority trials).

(Response) In response to these comments, FDA is deleting the ''safety and effectiveness comparable to the approved drug'' language from the final rule because of the confusion this language engendered. FDA did not intend to propose a new standard for major contribution to patient care with this language; in particular, FDA did not mean to suggest that direct proof of comparability to the already approved drug would be required (e.g., through non-inferiority trials). Instead, FDA intended to convey that major contribution to patient care determinations can be complex and encompass consideration of a number of factors that potentially implicate safety and effectiveness, which are evaluated on a case-by-case basis for each drug product. For more discussion of major contribution to patient care, see the responses to comments 9 and 15.

(Comment 15) Several comments asked for clarification of the meaning of ''major contribution to patient care.'' In particular, these comments asked FDA to reiterate and expand the list of factors that FDA had included in the preamble to the 1992 final rule, Orphan Drug Regulations (57 FR 62077 at 62079). The comments proposed the following additional factors: increased quality of life, reduced treatment burden, and improved patient compliance.

(Response) The following factors, when applicable to severe or life-threatening diseases, may in appropriate cases be taken into consideration when determining whether a drug makes a major contribution to patient care: convenient treatment location; duration of treatment; patient comfort; reduced treatment burden; advances in ease and comfort of drug administration; longer periods between doses; and potential for self-administration. FDA declines to add ''increased quality of life'' to this list because many factors already on the list may be viewed as increasing quality of life, such as increased patient comfort and longer periods between doses. FDA also declines to add ''improved patient compliance'' to the list of factors potentially informing whether a drug provides a major contribution to patient care, because FDA would expect improved patient compliance to be reflected in other factors already on this list (e.g., increased patient comfort, reduced treatment burden, etc.), if not otherwise reflected in greater safety or greater effectiveness showings for the drug. For more on major contribution to patient care, see the responses to comments 9 and 14.

(Comment 16) One comment asked FDA to delete the opening clause, ''in unusual cases,'' because major contribution to care findings should be more customary in light of recent protein engineering and extended release technologies, which allow for significant improvements in patient care.

(Response) In FDA's experience, showings of major contribution to patient care remain unusual. Although new technologies may increase the number of drugs found to make such major contributions, FDA still expects these showings to be less frequent than greater safety and greater effectiveness showings. FDA is therefore retaining the clause, ''in unusual cases.''

E. Name of the Drug

(Comment 17) One comment objected to the requirement to include a chemical name in the designation request at § 316.20(b)(4), if neither a generic nor trade name is available. Disclosing the chemical name (especially pre-patent) may put sensitive commercial information at risk, which could ''negatively impact the potential to secure intellectual property rights and thus reduce the incentives for further development.''

(Response) FDA advises that sponsors need not include a chemical name in the designation request as long as they include a meaningful descriptive name of the drug. The final rule, like the proposed rule, is phrased in the disjunctive: ''the chemical name *or* a meaningful descriptive name of the drug'' (emphasis added), if neither a generic nor trade name is available. By meaningful descriptive name, we mean a name that would be meaningful to the public. It could include information about the product class or type, the mechanism of action, how or where the product was derived, and other information as appropriate. An example of a meaningful descriptive name could be murine anti-CD30 monoclonal antibody, which describes the deoxyribonucleic acid (DNA) source, the cell being targeted by the product, and the product type. As described in the proposed rule (76 FR 64868 at 64872 to 64873), we do not consider internal business codes or other similar identifiers to be meaningful descriptive names.

F. Required Drug Description and Scientific Rationale in a Request for Orphan-Drug Designation

(Comment 18) One comment asked that FDA add the qualifier ''relevant'' to modify ''data'' in the phrase ''all data from in vitro laboratory studies'' at § 316.20(b)(4).

(Response) FDA agrees and has amended the final rule accordingly.

(Comment 19) One comment asked why FDA would limit the clinical data to ''clinical investigations of the drug in the rare disease or condition'' when there may be pharmacokinetic (PK) or pharmacodynamic (PD) data in other conditions that are relevant to the proposed orphan use.

(Response) FDA advises that such PK and PD data are not generally relevant or necessary to an orphan drug designation request, and so FDA is not amending the proposed rule to require such data as suggested. Sponsors may, however, choose to provide such data if they believe such data are relevant or necessary to their request, for example, to provide a plausible hypothesis of clinical superiority over a previously approved drug.

On its own initiative, FDA has revised the regulatory language, ''clinical investigations of the drug in the rare disease or condition,'' for clarity. In this final rule, FDA has replaced ''clinical investigations'' with ''clinical experience'' to reflect that FDA may in some cases consider clinical data from sources other than clinical investigations, for example, from well-documented case histories or significant human experience with the drug, as appropriate. FDA will assess the relevance and significance of such data on a case-by-case basis.

G. Responding to a Deficiency Letter From FDA on an Orphan-Drug Designation Request

(Comment 20) One comment asked FDA to clarify that having a designation request withdrawn or denied does not preclude re-submitting a request.

(Response) FDA agrees, although notes that eligibility for orphan-drug designation in terms of prevalence is evaluated at the time of the submission of the request (see § 316.21(b)). In the event a request is newly submitted after being withdrawn or denied, FDA will determine eligibility in terms of prevalence as of the date of the new submission. In response to this comment, FDA is considering whether to include language in its form letters to notify sponsors that they may submit a new request if their request is considered withdrawn or denied, but that eligibility in terms of prevalence will be evaluated at the time of any new submission.

Prompted by this comment, FDA has re-evaluated proposed § 316.24(a) for clarity and has made a ministerial edit. This edit makes clear that FDA will notify the sponsor whenever a request is considered voluntarily withdrawn, whether it is considered withdrawn because the sponsor failed to respond to a deficiency letter or request an extension of time to respond within 1 year, or because FDA denied the request for an extension of time. The language as proposed erroneously suggested that FDA would notify the sponsor in writing only in the latter instance.

H. Publication of Orphan-Drug Designations

(Comment 21) Five comments objected to possible disclosure by FDA of whether sponsors of designated drugs have submitted annual reports as required under § 316.30. In the preamble to the proposed rule (76 FR 64868 at 64873), FDA inquired whether such disclosure would help inform the public of the development status of orphan drugs. Many comments maintained that such information would likely create confusion and miscommunication, because failure to submit an annual report does not necessarily signal that the sponsor has ceased drug development. Many of these comments did, however, support broader disclosure of the development status of orphan drugs through means they considered more informative, such as: expanding the ClinicalTrials.gov database; devising and publishing an ''inactive'' status for orphan drug designations similar to the ''inactive'' status for Investigational New Drug

(IND) applications (see 21 CFR 312.42(g)); and publishing when drugs no longer have orphan-drug designation (e.g., because designation was voluntarily withdrawn by the sponsor). Some of these comments cautioned that any broader disclosure of orphan drug development status should be carefully tailored so as not to reveal highly sensitive commercial information that may violate legal protections and benefit only the sponsor's competitors, not patients with rare diseases.

(Response) FDA agrees that publishing whether or not sponsors have submitted annual reports as required under § 316.30 may not accurately inform the public as to the development status of orphan drugs. FDA has carefully considered the alternative disclosures suggested by the comments and has decided to adopt in this final rule one suggested approach: namely, to publish when drugs no longer have orphan-drug designation (either because the sponsor voluntarily withdrew designation or because FDA revoked designation under § 316.29).

FDA has amended § 316.28 to state that the publicly available cumulative posting of all drugs designated as orphan drugs, available on its Web site at *http://www.fda.gov/orphan/,* will include whether a drug no longer has designation and, if so, as of what date. The public was formerly able to deduce that a drug had lost designation from FDA's publication of hard copy quarterly lists of designated drugs: drugs no longer designated would appear on earlier hard copy lists but not on later ones. Once FDA switched to Internet publication, this information was no longer deducible owing to database limitations at the time. Once this rule takes effect, FDA will publish on the Internet a posting of drugs that, after the effective date of this rule, lose designation, but without specifying the reason (i.e., whether because the sponsor voluntarily withdrew designation or because FDA revoked designation under § 316.29). Publishing only the fact that a drug is no longer designated, and not also the underlying reason(s), mitigates any competitive concerns. Stakeholders may then choose to contact the sponsor for more information on the status of the drug's development. FDA advises sponsors that it will not publish when a designation request has been withdrawn; unlike designations, designation requests are generally not made public unless disclosed by the sponsor.

FDA has made conforming amendments to § 316.29 to reference this change to § 316.28. Relatedly, FDA has added a § 316.24(d) to this final rule to make express an option that has always existed for sponsors—that they can voluntarily withdraw a designation request, or a designation proper, at any time by requesting such a withdrawal in writing from FDA. FDA will acknowledge such withdrawal in a letter to the sponsor. Any current or pending benefits attendant to designation, such as orphan-exclusive approval, will cease once designation is voluntarily withdrawn from the date of FDA's acknowledgement letter. The same holds true when FDA has revoked designation under § 316.29. See § 316.29(b). Any benefits that have already vested, such as tax credits or user fee exemptions, would not be affected.

FDA has determined that a reproposal to reflect these edits is neither necessary for reasoned decisionmaking nor desirable as a matter of policy. As noted previously, the proposed rule (76 FR 64868 at 64873) stated that FDA was ''considering ways to make available to the public information about the status of development for designated orphan drugs'' and invited comments on whether to provide this information to the public through disclosure of the submission status of annual reports. All comments that addressed this topic supported broader disclosure of some sort on the development status of orphan drugs, just not disclosure of the submission status of annual reports. Many of these comments specifically recommended publishing when a drug loses designation. This information used to be deducible from FDA's hard copy publication of quarterly lists of designated drugs; once FDA switched to Internet publication, this information was no longer deducible owing to database limitations at the time.

Finally, FDA has on its own initiative updated § 316.28 to reflect that, as of at least a decade ago, FDA no longer places an annual list of designated drugs on file at the FDA Division of Dockets Management. This is a technical amendment reflecting established practice.

(Comment 22) One comment advised FDA that the best way to achieve compliance with the annual reporting requirement is through one-on-one interaction with sponsors who do not submit annual reports as required under § 316.30.

(Response) FDA agrees with this comment.

(Comment 23) One comment asked FDA to make public its finding on the acceptability of specific prevalence data to reduce uncertainty about designation requirements. ''This will allow sponsors to use prevalence data already assessed by FDA and thereby streamline the process for obtaining these data to complete applications.''

(Response) FDA does not accept this suggestion. As explained in the preamble to the 1991 proposed rule, Orphan Drug Regulations, FDA believes that such an approach would unfairly allow subsequent sponsors to get a ''free ride'' in designation requests: ''FDA believes it unfair to allow a subsequent sponsor to use a pioneer sponsor's research data for the purpose of obtaining orphan-drug designation when such research data would by law not otherwise be available to the subsequent sponsor'' (56 FR 3338 at 3340). Further, prevalence data are often specific to each designation request in terms of both the timing of the request and the properties of the drug for which the request is submitted. Under § 316.21(b), eligibility in terms of prevalence is determined at the time of the submission of the request. Under § 316.20(b)(6), the prevalence estimate may be narrowed owing to one or more properties of the drug that allow for the existence of an orphan subset (i.e., only a subset of persons with the disease or condition would be appropriate candidates for use of the drug). These two factors make prevalence determinations specific to each request and further counsel against FDA publicly disclosing prevalence data and the acceptability thereof.

(Comment 24) Two comments asked FDA to revise its publicly available posting of orphan designated drugs to include additional information. One of these comments asked that the posting include all designated biological products approved via a Biologics License Application (BLA) and granted orphan-drug exclusivity, along with the dates of grant and expiry; the other comment asked FDA to highlight when a designated drug is approved for the orphan use but does not receive orphan-drug exclusivity.

(Response) FDA advises that its current publicly available posting of orphan designated drugs, available on its Web site at *http://www.fda.gov/orphan/,* includes biological drug products licensed via BLA, in addition to drug products approved via a New Drug Application (NDA). FDA is in the process of adding to this database reference to any applicable orphan-drug exclusivity periods. Once this revision to the database is complete, the absence of such information may possibly indicate that the product did not receive orphan-drug exclusivity upon approval (or alternatively that the information has not yet been entered into the database).

Stakeholders may also contact sponsors directly for the information and, for drugs approved via NDA, review the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book), available electronically at *http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm*.

FDA is making a ministerial edit to § 316.34(b) in response to this comment, to clarify that the Orange Book includes only information about products approved under section 505 of the FD&C Act (21 U.S.C. 355). FDA is also adding an online address for the Orange Book.

I. FDA Recognition of Orphan-Drug Exclusive Approval

(Comment 25) Two comments objected to FDA approving an orphan-designated drug but withholding orphan-drug exclusivity, for example, if the drug is the same as a previously approved drug and clinical superiority is not demonstrated upon marketing approval. These comments contended that, under section 527 of the FD&C Act, orphan-drug exclusivity should automatically attach once a designated drug is approved for the rare disease or condition for which it was designated, whether or not it is the first drug to be approved for this use. One of these comments characterized FDA regulations at §§ 316.31(a) and 316.34(a) as apparently confirming this ''automatic award'' of exclusivity upon approval of any designated drug.

(Response) FDA disagrees. FDA has long interpreted the Orphan Drug Act to accord orphan exclusive approval only to the first drug approved for the disease or condition (see 56 FR 3338 at 3341). The statute cannot be logically read to confer exclusivity to every designated drug that gets approved, as these comments suggest.

Section 527 generally confers exclusivity by prohibiting FDA from approving later drugs after a previous drug has been designated and approved. ''[I]f the Secretary [] approves an application . . . for a drug designated under section 526 . . . the Secretary may not approve another application . . . for *such drug* . . . until the expiration of seven years from the date of the approval of the approved application.'' Section 527(a) (emphasis added). Courts construing this statute have held ''such drug'' to be ambiguous; they have further upheld FDA's regulatory scheme to require a showing of clinical superiority over a previously approved drug in order for the clinically superior drug to not be blocked by another sponsor's exclusivity and to be eligible for its own period of exclusivity. See, e.g., *Baker Norton Pharms.* v. *FDA,* 132 F. Supp. 2d 30, 37 (D.D.C. 2001).

Section 527 is also ambiguous on the question of whether a drug may be eligible for exclusivity when another drug that is the same has already been approved for the same use. See section 527(a) (referring to an approved drug and unapproved applications for such drug, but not to any drugs approved previously to the approved drug). Under FDA's longstanding interpretation, any such previously approved drug precludes exclusivity absent a showing of clinical superiority because sponsors could otherwise: (1) Obtain infinite, successive 7-year periods of exclusivity for the same drug for the same use when the previously approved drug had such exclusivity, known as ''evergreening,'' or (2) obtain an exclusivity period for a drug without providing any meaningful benefit to patients over previously approved therapies, when the previously approved drug did not have orphan exclusivity. Both results would be at odds with the Orphan Drug Act.

''Evergreening'' would allow orphan exclusivity to be extended indefinitely for the same drug for the same use without any meaningful benefit to patients, a result at odds with the 7-year exclusivity period provided by the statute. See *Baker,* 132 F. Supp. at 37 (noting with approval that, under FDA's interpretation, ''market exclusivity rights are limited in time to seven years, and granted only for a particular drug for a particular use''). Congress would not have prescribed a definite period of exclusivity and at the same time provided for means to indefinitely extend that period. Indeed, the legislative history reflects this by stating that even if multiple sponsors get designation for the same drug, ''only the first sponsor to be approved is awarded the seven year market exclusivity for that drug for the approved use.'' H.R. Rep. 100–473, at 6 (1987). Further, where the first approved drug does not have orphan designation or exclusivity, awarding orphan exclusivity to a second-in-time drug that has not been shown to be clinically superior to the first approved drug—as these comments suggest doing—would be incompatible with the core objective of the Orphan Drug Act, to encourage development of drugs that would not otherwise be developed and approved (not to encourage minor modifications to already approved drugs that confer no meaningful benefit to patients). See H.R. Rep. 97–840, Pt. 1, at 6 (1982); 56 FR 3338; *Genentech,* 676 F. Supp. at 305–06, 312.

FDA's longstanding interpretation of section 527—to accord orphan exclusive approval only to the first approved drug for the disease or condition (assuming it has been designated)—implements the exclusivity period as written, is consistent with FDA's regulatory framework, and best effectuates Congress' aim in enacting the Orphan Drug Act. FDA's interpretation is also consistent with the decisions of courts that have had occasion to address orphan exclusivity. See *Genentech,* 676 F. Supp. at 304 (orphan exclusivity ''is reserved for the first manufacturer to receive full FDA approval of its drug as safe and effective for commercial sale,'' even if multiple drugs have orphan designation); *cf. Baker,* 132 F. Supp. 2d at 31 (if two drugs are the same under FDA regulations, ''the second drug may not be approved for market exclusivity'').

Accordingly, FDA is retaining § 316.34(c) in this final rule to make clear that a designated drug will receive orphan-drug exclusivity upon approval only if the same drug has not been previously approved for the same orphan use: that is, if the drug is otherwise the same as a previously approved drug, it will receive exclusivity only upon a demonstration of clinical superiority. FDA is, however, amending the final rule slightly so that it reads: ''If a drug is otherwise the same drug as a previously approved drug for the same use or indication, FDA will not recognize orphan-drug exclusive approval if the sponsor fails to demonstrate upon approval that the drug is clinically superior to the previously approved drug.'' [5] This revision clarifies for sponsors that, even if they obtained orphan-drug designation for a drug without having to provide a plausible hypothesis of clinical superiority (because the same drug was not yet approved for the same orphan use), they will have to demonstrate clinical superiority in order to obtain orphan-drug exclusivity if—in the interim between their obtaining orphan-drug designation and marketing approval for their drug—the same drug is approved for the same use.[6] This longstanding interpretation gives best effect to the intent of the Orphan Drug Act, described previously.

This revision to § 316.34(c) also corrects a possible misunderstanding of the proposed rule. The proposed rule may have been read to suggest that, if a designation is based on a plausible hypothesis of clinical superiority, the

[5] The term ''upon approval'' in this context does not preclude the possibility that clinical superiority may be demonstrated in a supplemental submission for the drug after approval.

[6] FDA's form letters granting orphan-drug designation alert sponsors to this possibility.

sponsor can obtain orphan-drug exclusivity only by substantiating the precise hypothesis upon which the designation was based (e.g., this drug is safer than the same previously approved drug because of the elimination of a certain ingredient). Rather, under FDA's interpretation, orphan-drug exclusivity would attach to a designated drug that is otherwise the same as a previously approved drug as long as it is shown to be clinically superior upon approval, whether or not the showing of clinical superiority at the approval stage aligns with the plausible hypothesis of clinical superiority provided at the designation stage (e.g., if the drug is shown to be safer for a different reason or is instead shown to be more effective). FDA understands that a hypothesis of clinical superiority (required for orphan-drug designation) is often devised early in the drug development process, and that subsequent research may result in enhanced understanding of the drug and possibly even changes to the drug itself. To not recognize orphan-drug exclusivity for a designated drug that is demonstrated to be clinically superior to a previously approved drug that is otherwise the same, solely because the sponsor inaccurately hypothesized the basis for clinical superiority, would contravene the intent of the Orphan Drug Act. Recognizing exclusivity in this instance encourages the development of safer and more effective orphan drugs.

Finally, in response to the assertion in this comment that §§ 316.31(a) and 316.34(a) apparently ''confirm'' that all designated drugs receive orphan-drug exclusivity upon approval (whether or not they are the first such drug approved), FDA has slightly revised §§ 316.3(b)(12), 316.31(a) and 316.34(a) to clarify that FDA recognizes orphan-drug exclusivity for the designated drug only if the same drug has not already been approved for the same use or indication. This revision clarifies FDA's longstanding interpretation of these provisions, as noted previously. Because this interpretation was explained in the preamble to the proposed rule (76 FR 64868 at 64870 to 64873), and reflected in the proposed rule at § 316.34(c), FDA has determined that a reproposal to amend §§ 316.3(b)(12), 316.31(a), and 316.34(a) in this manner is not required.

(Comment 26) One comment asked FDA to confirm that head-to-head safety trials may not always be necessary to establish clinical superiority based on greater safety, under § 316.3(b)(3)(ii).

(Response) FDA agrees. The regulation at § 316.3(b)(3)(ii) expressly states that direct comparative clinical trials to demonstrate greater safety may be necessary in only ''some cases.'' (By contrast, the regulation at § 316.3(b)(3)(i) states that direct comparative clinical trials to demonstrate greater effectiveness is necessary in ''most cases.'') Instead of prescribing the precise type and amount of evidence necessary for demonstrating ''greater safety in a substantial portion of the target populations,'' the regulation at § 316.3(b)(3)(ii) allows FDA to determine on a case-by-case basis what type and amount of evidence suffice for a given drug.

J. Miscellaneous Comment

(Comment 27) One comment asked FDA to clarify when a sponsor may lose orphan-drug designation once the drug is in widespread use for the orphan indication.

(Response) A drug may be approved for multiples uses, some of which have orphan-drug designation and some of which do not. Simply because a drug is ''in widespread use'' does not mean that a sponsor will lose orphan-drug designation. A sponsor may lose designation if, for example, the drug was not in fact eligible for designation at the time the request was submitted or if the request contained an untrue statement of material fact. *See* § 316.29(a).

K. Initial Paperwork Burden Estimates

(Comment 27) One comment stated that FDA had underestimated the time it would take to prepare and submit each extension request under § 316.24(a), including time to develop and articulate a rationale for the requested extension and to obtain internal approval of the request before submission to FDA.

(Response) FDA has increased this estimate from 2 to 6 hours, as described in section VIII.

IV. Environmental Impact

FDA has determined under 21 CFR 25.30(h) and 25.31(a) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Legal Authority

FDA is issuing this final rule under the authority granted it by the Orphan Drug Act (Pub. L. 97–414). In enacting the Orphan Drug Act, Congress required FDA to issue regulations for the implementation of sections 525 and 526 of the FD&C Act, relating to written FDA recommendations on studies required for approval of marketing applications of orphan drugs and for the designation of eligible drugs as orphan drugs. In the **Federal Register** of December 29, 1992 (57 FR 62076) (1992 final rule), FDA issued a final rule for the implementation of these sections as well as for the implementation of section 527 of the FD&C Act and section 528 of the FD&C Act (21 U.S.C. 360dd), relating to exclusive marketing for orphan drugs and the encouragement of sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. This final rule clarifies regulatory provisions in the 1992 final rule and makes minor improvements to address issues that have arisen since that rule took effect.

This final rule furthers the main purpose of the Orphan Drug Act, to provide incentives to develop promising drugs for rare diseases or conditions that would otherwise not be developed and approved, including potentially safer or more effective orphan drugs. It does so in several ways by:

- Enhancing clarity for sponsors in seeking orphan-drug designations and orphan-drug exclusive marketing approval;
- Making clear that the possibility of orphan-drug exclusivity remains for sponsors who develop a potentially promising drug for use by the remaining persons affected by a rare disease or condition after the same drug has been approved for only a portion of that population;
- Clarifying that orphan-drug exclusivity is given to a designated drug upon approval only if it is the first drug approved for the orphan use, thus encouraging innovation in rare disease treatments; and
- Helping ensure that the orphan-drug designation request, at the time it is granted, is consistent with the purpose of the Orphan Drug Act despite a lapse of time between the date of submission of the initial request and a sponsor's response to a deficiency letter from FDA.

An additional source of authority for this rule is section 701 of the FD&C Act (21 U.S.C. 371). Under this section, FDA is authorized to issue regulations for the efficient enforcement of the FD&C Act. This final rule helps the efficient enforcement of the Orphan Drug Act provisions by enhancing clarity and certainty in FDA's administration of the orphan drug program.

VI. Implementation Plan

These regulatory changes take effect 60 days after the date of publication of the final rule. The final rule applies only to original orphan-designation

requests submitted on or after the effective date of the final rule. It does not apply to: (1) Amendments submitted on or after the effective date regarding previously submitted designation requests, or (2) responses to deficiency letters submitted on or after the effective date regarding previously submitted requests. The final rule has no effect on the scope of or eligibility for orphan-drug exclusive approval because it merely clarifies existing and longstanding FDA practice. Under this final rule, FDA will publicize if a drug no longer has designation only if the loss of designation occurs after the effective date of the rule (either because of voluntary withdrawal by the sponsor or because of revocation by FDA).

VII. Executive Order 13132: Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these requirements is provided in the paragraphs that follow with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Orphan Drug Regulations

Description: The rule finalizes revisions to the Orphan Drug regulations that clarify FDA policy and make minor improvements. The revisions are intended to assist sponsors who are seeking and who have obtained orphan-drug designations, as well as FDA in its administration of the orphan drug program. For the initial PRA analysis, FDA estimated the annual reporting burdens for the two collections of information included in the proposed rule that were not already included in part 316 and already approved by OMB in accordance with the PRA (44 U.S.C. 3501–3520), under OMB control number 0910–0167. For this PRA analysis, FDA likewise estimates the annual reporting burdens for these two collections of information, which are being finalized as originally proposed.

One requirement is that sponsors include in requests a chemical or meaningful descriptive name of the drug, if neither a trade name nor a generic name is available. By providing such information in the request for designation, sponsors will help ensure that the name that FDA ultimately publishes under § 316.28 upon designation of the product is accurate and meaningful to the public. Because sponsors are already required to include a description of the drug in requests for designation, the new requirement to include a chemical or meaningful descriptive name is not expected to require much additional time or effort from sponsors.

Based on historical data concerning the number of designation requests for which neither a trade name nor a generic name for the drug is available, FDA expects that about 20 requests per year would be affected by this requirement. FDA estimates that it will take approximately 0.2 hours, or 12 minutes, for sponsors to submit this information. This estimate reflects both the length of time likely required to submit the chemical name of the drug (less than 0.2 hours) and the length of time likely required to submit a meaningful descriptive name if a chemical name is not readily available (more than 0.2 hours).

Another requirement is that sponsors respond to deficiency letters from FDA on designation requests within 1 year of issuance of the deficiency letter, unless within that timeframe the sponsor requests in writing an extension of time to respond. FDA will grant all reasonable requests for an extension. In the event the sponsor fails to respond to the deficiency or request an extension of time to respond within the 1-year timeframe, FDA may consider the designation request voluntarily withdrawn.

FDA believes this revision is necessary to ensure that deficient designation requests do not become ''stale'' by the time they are granted, such that the basis for the initial request may no longer hold (i.e., the prevalence of the disease or condition may now exceed 200,000). Granting such designations despite a lapse of years and change in factual circumstances concerning the disease or condition in question may not serve the primary purpose of the Orphan Drug Act to provide incentives for the development of drug products for ''rare diseases or conditions'' as defined in section 526 of the FD&C Act. This situation—where a request for designation languishes for a year or more before being granted—is distinct from situations where a designation request is granted but development of the drug languishes, whether for scientific, business, or other reasons.

Based on historical data concerning the number of deficiency letters that FDA has sent and the number of sponsors who have taken longer than a year to respond, FDA estimates that it will receive approximately 10 written requests each year for an extension of time to respond. This number is likely an overestimate, because it is based on historical data in the absence of any regulatory deadline for sponsors to respond; FDA believes that at least some of the sponsors who have taken longer than a year to respond have been capable of responding earlier, but did not do so because they did not need to. In the initial PRA analysis, FDA estimated that it would take approximately 2 hours to prepare and submit each extension request, including time to develop and articulate a rationale for the requested extension and to obtain internal approval of the request before submission to FDA. In response to one comment that 2 hours was an underestimate of the time required, FDA has increased this estimate to 6 hours to better account for the time needed to obtain internal approval of a request before submission to FDA.

Description of Respondents: Persons and businesses, including small businesses and manufacturers.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
316.20(b)(2)	20	1	20	* 0.2	4
316.24(a)	10		1	6	60
Total Burden Hours					64

[1] There are no capital costs or operating and maintenance costs associated with this collection of information. Except with respect to the revisions addressed immediately previously, the revisions in this final rule merely clarify existing regulatory language and do not constitute a substantive or material modification to the approved collections of information in current part 316. Cf. 5 CFR 1320.5(g). The collections of information in current part 316 have been approved by OMB in accordance with the PRA (44 U.S.C. 3501–3520), under OMB control number 0910–0167.

* 12 minutes.

In compliance with the PRA (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this final rule to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IX. Analysis of Impacts

FDA has examined the impacts of the rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule primarily clarifies current practice and any costs would be very small, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this rule to result in any 1-year expenditure that would meet or exceed this amount.

A. Background

Our experience with orphan-drug designation requests over many years has led us to conclude that sponsors are confused by some portions of the current regulatory language. The Agency receives dozens of requests for orphan-drug designation each year that are deficient in some way that would prevent designation. We observe the same types of deficiencies suggesting some problematic areas in our regulations.

Of the 324 requests for orphan-drug designation we received in 2010, 124 were denied or placed in abeyance so that the sponsor could submit additional material to respond to the deficiencies. Of these, 79 were deficient because they did not identify an appropriate ''medically plausible subset'' of a population with a non-rare disease or condition. That nearly a quarter of the designation requests were deficient in their subset analysis, and that problems with population subsets constituted over all half of the deficiencies, highlights the need to clarify existing regulatory language regarding subsets.

The confusion about regulatory language was not limited to issues regarding population subsets. Many designation requests were deficient because the submitted drug description was not adequate to establish whether the drug was the same as one that has already been approved. There were continuing problems with requests for drugs that are in fact the same as drugs already approved but lack necessary information regarding clinical superiority. Other requests lacked the data to support the scientific rationale for the use of the drug in a rare disease or condition. Addressing these deficiencies and resolving sponsor inquiries consumes sponsor and FDA resources and extends the orphan-drug designation process. The process would be less costly to sponsors and FDA if sponsors had an authoritative source of information about basic program requirements.

Basic program requirements are part of Federal regulation; clarifying regulatory language to reduce costly confusion would have to be done through rulemaking at the Federal level. This final rule clarifies regulatory language to reduce sponsor and FDA costs and streamline the orphan-drug designation process.

B. Benefits and Costs of the Proposed Rule

This final rule reduces costs to sponsors who might otherwise submit deficient orphan-drug designation requests or face additional costs to determine program requirements. It benefits sponsors and promotes public health by clarifying requirements for sponsors who might otherwise be discouraged from submitting designation requests when their drug is in fact eligible for orphan-drug designation. The rule also reduces costs to FDA from responding to sponsor inquiries and deficient designation requests. There are small costs associated with the requirement that sponsors either respond to deficiency letters within a year or obtain an extension of time to respond.

We clarify what population or disease subsets may be eligible for orphan-drug designation (§ 316.3(b)(13) and § 316.20(b)(6)). This action merely clarifies longstanding policy and should reduce uncertainty about the requirements for orphan-drug designation, thus resulting in fewer requests that do not result in orphan-

drug designation. In addition, some sponsors may realize that their drug is not eligible for orphan-drug designation. Such sponsors would save the cost they would have otherwise incurred in submitting a request. FDA has recently (76 FR 3911) estimated a burden of 150 hours to complete a designation request. At a benefit-adjusted hourly wage of about $46 for a regulatory affairs official, sponsors not submitting a request that cannot be granted would avoid $6,900 in labor costs.[7] Under this rule, other sponsors would avoid the cost they would have otherwise incurred addressing the subset deficiency. We do not have a precise estimate of the time required to respond to a deficiency letter; using 40 hours as a rough estimate implies $1,840 in avoided labor costs. We do not possess a reliable estimate for the number of avoided deficiency letters, but assuming FDA receives 79 subset-deficient requests each year and one-half would not occur with the clarified regulatory language, sponsors would avoid $72,680 in additional labor costs. FDA would also avoid costs from responding to these requests.

FDA's longstanding interpretation of the Orphan Drug Act and Orphan Drug regulations is that a designation request for a drug that is otherwise the same as a drug previously approved for the same use must include a plausible hypothesis of clinical superiority, regardless of whether the already approved drug received orphan-drug designation and exclusivity. FDA continues to receive requests that do not result in orphan-drug designation because this interpretation is not explicit in current regulation. This rule would make the regulatory language explicitly state FDA's interpretation, reducing costs to sponsors and FDA by reducing the number of deficient orphan-drug designation requests.

FDA's longstanding practice has been that if a drug is approved for only select indications or uses within a rare disease or condition for which the drug is designated, FDA may grant orphan-drug designation and orphan-drug exclusive approval for use of the same drug in one or more of the remaining (not previously approved) indications or uses within the rare disease or condition without requiring any showing of clinical superiority. Current § 316.31 does not explicitly mention this prospect, which could deter confused sponsors from pursuing designation for use of the drug in remaining indications or uses for which the drug has not yet been approved. Clarifying this provision would not change Agency policy but would benefit sponsors and public health by reducing the risk of a sponsor failing to pursue designation when it would otherwise do so.

We modify and clarify our requirements for the drug name. Current regulations require the sponsor to submit the generic and trade name of the drug, but do not specify how to name a drug for which there is no generic name or trade name. In the past, sponsors have provided FDA with their internal business codes, which are meaningless to the general public. We require that a drug that has neither a generic nor a trade name be identified according to its chemical name or a meaningful descriptive name (i.e., one that would be meaningful to the public if published). Chemical and descriptive names are readily accessible to the sponsor and could be included in a designation request as easily as an internal business code and any costs would be too small to meaningfully quantify.

We clarify our requirements for the drug description and for the data to support a drug's scientific rationale in an orphan-drug designation request. Some requests for orphan-drug designation cannot be acted upon because the drug descriptions are not adequate to determine whether the drug in the submission is the same as a previously approved drug. This rule clarifies the required drug description in § 316.20(b)(4), reducing the frequency of deficient requests. Some requests lack the data to support a scientific rationale while others include substantial additional data not needed to obtain designation. In both situations, sponsors incur costs that could be avoided with clearer requirements. We do not know the frequency of these data problems nor do we know the costs associated with them, but this rule reduces sponsor and FDA costs.

We eliminate § 316.20(b)(9), which requires that the sponsor submitting the request state whether it is the real party in interest of the development and the intended or actual production and sales of the product. This provision merely obtains information from the sponsor; it does not provide a basis to disqualify any entity from pursuing orphan-drug designation. There is no known use for the information and it is our understanding that this provision may be discouraging sponsors from using agents to submit requests on their behalf, potentially increasing the cost to obtain orphan-drug designation. We do not possess a reliable estimate for this cost. Eliminating this provision clarifies our longstanding policy to accept submissions from agents, which may reduce sponsor costs. Halting the collection of information for which there is no known purpose would not negatively impact public health.

We clarify the requirement regarding the timing of orphan-drug designation requests (§ 316.23(a)). A sponsor may not submit an orphan-drug designation request after it has submitted a marketing application for the drug for that use. It is not clear in the current regulatory language that one sponsor's marketing application would not prevent a different sponsor from submitting a request for orphan-drug designation for the same drug for the same orphan use and that this subsequent sponsor would not have to submit a plausible hypothesis of clinical superiority. Clarifying current policy benefits sponsors and public health by reducing the likelihood of a confused sponsor failing to seek orphan-drug designation for an eligible product.

We impose a 1-year time limit for sponsors to respond to deficiency letters or request a time extension (§ 316.24(a)). Current regulations do not impose time limits on sponsors replying to FDA deficiency letters and we have no mechanism to encourage sponsors to continue to actively pursue designation. Based on our experience with the time required to address particular submission deficiencies and the observed variation in time for sponsors to respond, some submission requests do not appear to be part of an active effort to obtain orphan-drug designation. We know of no public health benefit from open inactive designation requests. We do not know if they exist because sponsors gain nothing from the cost of formally withdrawing a request or because there may be a strategic advantage to an inactive request for designation. Sponsors who would otherwise respond to a deficiency letter within 1 year would be unaffected by this proposal. Sponsors actively pursuing designation but needing more than 1 year to respond to a deficiency letter would be expected to submit a time extension request to FDA. We assume approval for all extension requests from sponsors actively pursuing orphan-drug designation and estimate a request would require 6 hours of time from a regulatory affairs specialist. At a benefit-adjusted hourly wage of $46, the cost to submit an extension request is $276. Based on our

[7] 2010 National Industry-Specific Occupational Employment and Wage Estimates, U.S. Department of Labor Statistics, last modified May 17, 2011 (*www.bls.gov/oes/current/naics4_325400.htm*); mean compliance officer wage rate of $35.28 for pharmaceutical and medicine manufacturing (North American Industry Classification System (NAICS) 325400) plus a 30-percent increase for benefits.

experience with deficiency letters and the frequency of responses requiring more than 1 year, we estimate 10 requests for additional time each year. The estimated annual cost of this provision is $2,760. We assume sponsors not actively pursuing designation would not obtain extensions and their requests would be considered to be withdrawn 1 year after the deficiency letter. We do not possess a reliable estimate of the number of designation requests that would be withdrawn under this proposal. Withdrawing inactive designation requests would improve information about potential future orphan drugs, which would be beneficial to potential sponsors and to the general public. There is at least a potential for a cost to some sponsors, as we cannot rule out the possibility of some small advantage to holding an inactive designation request. Nevertheless, we estimate the cost of a withdrawal in this case to be very small and to be extremely small relative to the benefits of improved public information and the streamlined orphan-drug designation process.

We clarify that sponsors can voluntarily withdraw a designation request, or designation proper, at any time by submitting a written request to FDA (§ 316.24(d)). This is consistent with current practice and imposes no new costs on sponsors. Some sponsors are unaware of this option so this will save sponsors and FDA costs associated with unnecessary inquiries.

We clarify that FDA may refuse to grant a designation request if the request is otherwise ineligible for designation under part 316 (§ 316.25(b)). Because this change merely codifies existing practice, it is not expected to impose any new costs.

This rule provides that FDA will publish the fact a drug is no longer designated (§ 316.28(e)). Sponsors who may otherwise have been deterred from developing a drug because of another sponsor's designation of the drug may now seek their own designation for that drug and develop it upon learning that the first sponsor no longer has designation. The cost to FDA to publish this information is too small to reliably estimate.

According to longstanding policy, FDA does not recognize orphan-drug exclusive approval when the sponsor of a drug that is otherwise the same as a drug already approved for the same use fails to demonstrate clinical superiority upon approval. We make this policy explicit by adding proposed § 316.34(c). This clarification is applicable to only a very small portion of designated drugs and benefits would be too small to reliably estimate.

We do not possess a single bottom line estimate for the total monetized benefit of this rule. Avoiding half of the designation requests that are deficient because of problems establishing population subsets would save sponsors an estimated $73,000 annually. Subset problems account for more than half of all deficiencies, so we estimate the other clarifications to reduce deficient requests would reduce sponsor costs by an additional amount less than $73,000. The total estimated cost of this rule is an annual $2,760, attributable to the submission of requests for additional time to respond to deficiency letters.

C. Small Business Analysis

This rule applies to the sponsors of orphan-drug designation requests. According to the Table of Small Business Size Standards, the U.S. Small Business Administration considers pharmaceutical preparation manufacturing entities (NAICS 325412) with 750 or fewer employees and biological product (except diagnostic) manufacturing entities (NAICS 325414) with 500 or fewer employees to be small.[8] According to the 2007 Economic Census, annual shipments for the 284 establishments in NAICS 325412 with 0 to 4 employees are $240 million, which is $840,000 per establishment. Total annual shipments for the 250 establishments in NAICS 325414 with 0 to 49 employees (the smallest group with value of shipment data) are $720 million, which is $2.9 million per establishment.

Most of the provisions of this rule clarify regulatory language consistent with current practice, imposing no new costs. The 1-year time limit to respond to FDA deficiency letters would result in estimated costs of $276 per extension request. Costs from the withdrawal of inactive submissions would be too small to reliably quantify. A common threshold for determining a significant impact is 1 percent of annual shipments. Because the estimated cost of this rule is approximately 1/33 of 1 percent of annual shipments for the smallest affected establishments, we conclude this rule does not constitute a significant impact on a substantial number of small entities.

List of Subjects in 21 CFR Part 316

Administrative practice and procedure, Investigations, Medical research, Drugs, Orphan Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 316 is amended as follows:

PART 316—ORPHAN DRUGS

■ 1. The authority citation for 21 CFR part 316 continues to read as follows:

Authority: 21 U.S.C. 360aa, 360bb, 360cc, 360dd, 371.

■ 2. Section 316.1 is amended by revising paragraphs (a)(1)(iii) and (a)(2) to read as follows:

§ 316.1 Scope of this part.

(a) * * *

(1) * * *

(iii) Requests for gaining exclusive approval for a drug for a rare disease or condition.

(2) Allowing a sponsor to provide an investigational drug under a treatment protocol to patients who need the drug for treatment of a rare disease or condition.

* * * * *

■ 3. Section 316.3 is amended by revising paragraphs (b)(3) introductory text, (b)(3)(i), and (b)(12), by redesignating paragraphs (b)(13) and (b)(14) as paragraphs (b)(14) and (b)(15), respectively, and by adding a new paragraph (b)(13) to read as follows:

§ 316.3 Definitions.

* * * * *

(b) * * *

(3) *Clinically superior* means that a drug is shown to provide a significant therapeutic advantage over and above that provided by an approved drug (that is otherwise the same drug) in one or more of the following ways:

(i) Greater effectiveness than an approved drug (as assessed by effect on a clinically meaningful endpoint in adequate and well controlled clinical trials). Generally, this would represent the same kind of evidence needed to support a comparative effectiveness claim for two different drugs; in most cases, direct comparative clinical trials would be necessary; or

* * * * *

(12) *Orphan-drug exclusive approval* or *exclusive approval* means that, effective on the date of FDA approval as stated in the approval letter of a marketing application for a sponsor of a designated orphan drug, no approval will be given to a subsequent sponsor of the same drug for the same use or indication for 7 years, except as

[8] U. S. Small Business Administration, ''Table of Small Business Size Standards Matched to North American Industry Classification System Codes,'' November 5, 2010. *http://www.sba.gov/sites/default/files/Size_Standards_Table.pdf*

otherwise provided by law or in this part. A designated drug will receive orphan-drug exclusive approval only if the same drug has not already been approved for the same use or indication.

(13) *Orphan subset of a non-rare disease or condition (''orphan subset'')* means that use of the drug in a subset of persons with a non-rare disease or condition may be appropriate but use of the drug outside of that subset (in the remaining persons with the non-rare disease or condition) would be inappropriate owing to some property(ies) of the drug, for example, drug toxicity, mechanism of action, or previous clinical experience with the drug.

* * * * *

■ 4. Section 316.4 is revised to read as follows:

§ 316.4 Address for submissions.

All correspondence and requests for FDA action under the provisions of this rule should be addressed as follows: Office of Orphan Products Development, Food and Drug Administration, Bldg. 32, Rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993.

■ 5. Section 316.20 is amended by revising paragraphs (a), (b)(2), (b)(3), (b)(4), (b)(5), and (b)(6), and by removing paragraph (b)(9) to read as follows:

§ 316.20 Content and format of a request for orphan-drug designation.

(a) A sponsor that submits a request for orphan-drug designation of a drug for a specified rare disease or condition shall submit each request in the form and containing the information required in paragraph (b) of this section. A sponsor may request orphan-drug designation of a previously unapproved drug, or of a new use for an already marketed drug. In addition, a sponsor of a drug that is otherwise the same drug as an already approved drug may seek and obtain orphan-drug designation for the subsequent drug for the same rare disease or condition if it can present a plausible hypothesis that its drug may be clinically superior to the first drug. More than one sponsor may receive orphan-drug designation of the same drug for the same rare disease or condition, but each sponsor seeking orphan-drug designation must file a complete request for designation as provided in paragraph (b) of this section.

(b) * * *

(2) The name and address of the sponsor; the name of the sponsor's primary contact person and/or resident agent including title, address, telephone number, and email address; the generic and trade name, if any, of the drug, or, if neither is available, the chemical name or a meaningful descriptive name of the drug; and the name and address of the source of the drug if it is not manufactured by the sponsor.

(3) A description of the rare disease or condition for which the drug is being or will be investigated, the proposed use of the drug, and the reasons why such therapy is needed.

(4) A description of the drug, to include the identity of the active moiety if it is a drug composed of small molecules, or of the principal molecular structural features if it is composed of macromolecules; its physical and chemical properties, if these characteristics can be determined; and a discussion of the scientific rationale to establish a medically plausible basis for the use of the drug for the rare disease or condition, including all relevant data from in vitro laboratory studies, preclinical efficacy studies conducted in an animal model for the human disease or condition, and clinical experience with the drug in the rare disease or condition that are available to the sponsor, whether positive, negative, or inconclusive. Animal toxicology studies are generally not relevant to a request for orphan-drug designation. Copies of pertinent unpublished and published papers are also required.

(5) Where the sponsor of a drug that is otherwise the same drug as an already approved drug seeks orphan-drug designation for the subsequent drug for the same rare disease or condition, an explanation of why the proposed variation may be clinically superior to the first drug.

(6) Where a sponsor requests orphan-drug designation for a drug for only a subset of persons with a particular disease or condition that otherwise affects 200,000 or more people (''orphan subset''), a demonstration that, due to one or more properties of the drug, the remaining persons with such disease or condition would not be appropriate candidates for use of the drug.

* * * * *

■ 6. Section 316.21 is amended by revising paragraph (a)(1) and the introductory text of paragraph (b) to read as follows:

§ 316.21 Verification of orphan-drug status.

(a) * * *

(1) Documentation as described in paragraph (b) of this section that the number of people affected by the disease or condition for which the drug is to be developed is fewer than 200,000 persons; or

* * * * *

(b) For the purpose of documenting that the number of people affected by the disease or condition for which the drug is to be developed is less than 200,000 persons, ''prevalence'' is defined as the number of persons in the United States who have been diagnosed as having the disease or condition at the time of the submission of the request for orphan-drug designation. To document the number of persons in the United States who have the disease or condition for which the drug is to be developed, the sponsor shall submit to FDA evidence showing:

* * * * *

■ 7. Section 316.22 is revised to read as follows:

§ 316.22 Permanent-resident agent for foreign sponsor.

Every foreign sponsor that seeks orphan-drug designation shall name a permanent resident of the United States as the sponsor's agent upon whom service of all processes, notices, orders, decisions, requirements, and other communications may be made on behalf of the sponsor. Notifications of changes in such agents or changes of address of agents should preferably be provided in advance, but not later than 60 days after the effective date of such changes. The permanent-resident agent may be an individual, firm, or domestic corporation and may represent any number of sponsors. The name of the permanent-resident agent, address, telephone number, and email address shall be provided to: Office of Orphan Products Development, Food and Drug Administration, Bldg. 32, rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993.

■ 8. Section 316.23 is revised to read as follows:

§ 316.23 Timing of requests for orphan-drug designation; designation of already approved drugs.

(a) A sponsor may request orphan-drug designation at any time in its drug development process prior to the time that sponsor submits a marketing application for the drug for the same rare disease or condition.

(b) A sponsor may request orphan-drug designation of an already approved drug for an unapproved use without regard to whether the prior marketing approval was for a rare disease or condition.

■ 9. Section 316.24 is amended by revising the section heading, redesignating paragraphs (a) and (b) as

paragraphs (b) and (c), respectively, and by adding new paragraphs (a) and (d) to read as follows:

§ 316.24 Deficiency letters and granting orphan-drug designation.

(a) FDA will send a deficiency letter to the sponsor if the request for orphan-drug designation lacks information required under §§ 316.20 and 316.21, or contains inaccurate or incomplete information. FDA may consider a designation request voluntarily withdrawn if the sponsor fails to respond to the deficiency letter within 1 year of issuance of the deficiency letter, unless within that same timeframe the sponsor requests in writing an extension of time to respond. This request must include the reason(s) for the requested extension and the length of time of the requested extension. FDA will grant all reasonable requests for an extension. In the event FDA denies a request for an extension of time, FDA may consider the designation request voluntarily withdrawn. In the event FDA considers a designation request voluntarily withdrawn, FDA will so notify the sponsor in writing.

* * * * *

(d) A sponsor may voluntarily withdraw an orphan-drug designation request or an orphan-drug designation at any time after the request is submitted or granted, respectively, by submitting a written request for withdrawal to FDA. FDA will acknowledge such withdrawal in a letter to the sponsor. Any benefits attendant to designation (such as orphan-exclusive approval) will cease once designation is voluntarily withdrawn, from the date of FDA's acknowledgement letter. If a sponsor voluntarily withdraws designation, FDA will publicize such withdrawal in accordance with § 316.28.

■ 10. Section 316.25 is amended by revising paragraphs (a)(1)(ii), (a)(3), and (b) to read as follows:

§ 316.25 Refusal to grant orphan-drug designation.

(a) * * *

(1) * * *

(ii) Where the drug is intended for prevention, diagnosis, or treatment of a disease or condition affecting 200,000 or more people in the United States, the sponsor has failed to demonstrate that there is no reasonable expectation that development and production costs will be recovered from sales of the drug for such disease or condition in the United States. A sponsor's failure to comply with § 316.21 shall constitute a failure to make the demonstration required in this paragraph.

* * * * *

(3) The drug is otherwise the same drug as an already approved drug for the same rare disease or condition and the sponsor has not submitted a medically plausible hypothesis for the possible clinical superiority of the subsequent drug.

(b) FDA may refuse to grant a request for orphan-drug designation if the request for designation contains an untrue statement of material fact or omits material information or if the request is otherwise ineligible under this part.

■ 11. Section 316.26 is revised to read as follows:

§ 316.26 Amendment to orphan-drug designation.

(a) At any time prior to approval of a marketing application for a designated orphan drug, the sponsor holding designation may apply for an amendment to the designated use if the proposed change is due to new and unexpected findings in research on the drug, information arising from FDA recommendations, or unforeseen developments in treatment or diagnosis of the disease or condition.

(b) FDA will grant the amendment if it finds that the initial designation request was made in good faith and that the amendment is intended to conform the orphan-drug designation to the results of unanticipated research findings, to unforeseen developments in the treatment or diagnosis of the disease or condition, or to changes based on FDA recommendations, and that, as of the date of the submission of the amendment request, the amendment would not result in exceeding the prevalence or cost recovery thresholds in § 316.21(a)(1) or (a)(2) upon which the drug was originally designated.

■ 12. Section 316.28 is revised to read as follows:

§ 316.28 Publication of orphan-drug designations.

Each month FDA will update a publicly available cumulative posting of all drugs designated as orphan drugs. These postings will contain the following information:

(a) The name and address of the sponsor;

(b) The generic name and trade name, if any, or, if neither is available, the chemical name or a meaningful descriptive name of the drug;

(c) The date of the granting of orphan-drug designation;

(d) The designated use in the rare disease or condition; and

(e) If the drug loses designation after August 12, 2013, the date of it no longer having designation.

■ 13. Section 316.29 is amended by adding a new paragraph (d) to read as follows:

§ 316.29 Revocation of orphan-drug designation.

* * * * *

(d) If FDA revokes orphan-drug designation, FDA will publicize that the drug is no longer designated in accordance with § 316.28(e).

■ 14. Section 316.31 is amended by revising the introductory text of paragraph (a), by redesignating paragraph (b) as paragraph (c), by revising newly redesignated paragraph (c), and by adding new paragraph (b) to read as follows:

§ 316.31 Scope of orphan-drug exclusive approval.

(a) FDA may approve a sponsor's marketing application for a designated orphan drug for use in the rare disease or condition for which the drug was designated, or for select indication(s) or use(s) within the rare disease or condition for which the drug was designated. Unless FDA previously approved the same drug for the same use or indication, FDA will not approve another sponsor's marketing application for the same drug for the same use or indication before the expiration of 7 years from the date of such approval as stated in the approval letter from FDA, except that such a marketing application can be approved sooner if, and at such time as, any of the following occurs:

* * * * *

(b) Orphan-drug exclusive approval protects only the approved indication or use of a designated drug. If such approval is limited to only particular indication(s) or uses(s) within the rare disease or condition for which the drug was designated, FDA may later approve the drug for additional indication(s) or uses(s) within the rare disease or condition not protected by the exclusive approval. If the sponsor who obtains approval for these new indication(s) or uses(s) has orphan-drug designation for the drug for the rare disease or condition, FDA will recognize a new orphan-drug exclusive approval for these new (not previously approved) indication(s) or use(s) from the date of approval of the drug for such new indication(s) or use(s).

(c) If a sponsor's marketing application for a drug product is determined not to be approvable because approval is barred under section 527 of the Federal Food, Drug, and Cosmetic Act until the expiration of

the period of exclusive marketing of another drug, FDA will so notify the sponsor in writing.

■ 15. Section 316.34 is revised to read as follows:

§ 316.34 FDA recognition of exclusive approval.

(a) FDA will send the sponsor (or, the permanent-resident agent, if applicable) timely written notice recognizing exclusive approval once the marketing application for a designated orphan-drug product has been approved, if the same drug has not already been approved for the same use or indication. The written notice will inform the sponsor of the requirements for maintaining orphan-drug exclusive approval for the full 7-year term of exclusive approval.

(b) When a marketing application is approved under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) for a designated orphan drug that qualifies for exclusive approval, FDA will publish in its publication entitled ''Approved Drug Products With Therapeutic Equivalence Evaluations'' information identifying the sponsor, the drug, and the date of termination of the orphan-drug exclusive approval. A subscription to this publication and its monthly cumulative supplements is available from the Superintendent of Documents, Government Printing Office, Washington, DC 20402–9325, and is also available online at *http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.*

(c) If a drug is otherwise the same drug as a previously approved drug for the same use or indication, FDA will not recognize orphan-drug exclusive approval if the sponsor fails to demonstrate upon approval that the drug is clinically superior to the previously approved drug.

■ 16. Section 316.50 is revised to read as follows:

§ 316.50 Guidance documents.

FDA's Office of Orphan Products Development will maintain and make publicly available a list of guidance documents that apply to the regulations in this part. The list is maintained on the Internet and is published annually in the **Federal Register**. A request for a copy of the list should be directed to the Office of Orphan Products Development, Food and Drug Administration, Bldg. 32, rm. 5271, 10903 New Hampshire Ave., Silver Spring, MD 20993.

Dated: June 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13930 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2013–0369]

RIN 1625–AA08

Special Local Regulation; Kelley's Island Swim, Lake Erie; Kelley's Island, Lakeside, OH

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will regulate vessel movement in portions of Lake Erie during the annual Kelley's Island Swim from. This special local regulated area is necessary to protect swimmers from vessel traffic.

DATES: The regulations in 33 CFR 100.921 will be enforced between 7 a.m. and 11 a.m. on July 10, 2013.

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email MST2 Annaliese Ennis, Assistant Waterways Branch Chief, Marine Safety Unit Toledo, 420 Madison Ave., Suite 700, Toledo, OH 43604; telephone (419) 418–6041; email *Annaliese.K.Ennis@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the special local regulations listed in 33 CFR 100.921 Special Local Regulation; Kelley's Island Swim, Lake Erie, Lakeside, OH, which was published in the December 3, 2012, issue of the **Federal Register** (77 FR 71531). These special local regulations will be enforced from 7 a.m. until 11 a.m. on July 10, 2013. Pursuant to 33 U.S.C. 1236 and 33 CFR 27.3, those who fail to comply with the special local regulations in 33 CFR 100.921 during this enforcement period will be subject to a civil penalty of up to $8,000.

Under the provisions of 33 CFR 100.921, vessels transiting within the regulated area shall travel at a no-wake speed and remain vigilant for event participants and safety craft. Additionally, vessels shall yield right-of-way for event participants and event safety craft and shall follow directions given by the Coast Guard's on-scene representative or by event representatives during the event. The ''on-scene representative'' of the Captain of the Port Detroit is any Coast Guard commissioned, warrant, or petty officer who has been designated by the Captain of the Port Detroit to act on his behalf. The on-scene representative of the Captain of the Port Detroit will be aboard either a Coast Guard or Coast Guard Auxiliary vessel. The Captain of the Port, Sector Detroit or his designated on scene representative may be contacted via VHF Channel 16.

This notice is issued under the authority of 33 CFR 100.921 and 5 U.S.C. 552(a).

Dated: May 28, 2013.

J. E. Ogden,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2013–13906 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Parts 100 and 165

[Docket No. USCG–2012–1057]

Special Local Regulations and Safety Zones; Recurring Events in Northern New England

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulations.

SUMMARY: The Coast Guard will enforce the events outlined in Tables 1 and 2 taking place throughout the Sector Northern New England Captain of the Port Zone. This action is necessary to protect marine traffic and spectators from the hazards associated with powerboat races, regattas, boat parades, rowing and paddling boat races, swim events, and fireworks displays. During the enforcement period, no person or vessel may enter the Special Local Regulation area or Safety Zone without permission of the Captain of the Port.

DATES: The marine events listed in 33 CFR 100.120 and 33 CFR 165.171 will take place during the times and dates specified in Tables 1 and 2 in **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: If you have questions on this notice, call or email Ensign Elizabeth V. Morris, Waterways Management Division at Coast Guard Sector Northern New England, telephone 207–767–0398, email *Elizabeth.V.Morris@uscg.mil.*

SUPPLEMENTARY INFORMATION: The Coast Guard will enforce the Special Local

Regulations and Safety Zones listed in 33 CFR 100.120 and 33 CFR 165.171. These regulations will be enforced for the duration of each event, on or about the dates indicated in TABLES 1 and 2.

TABLE 1—(33 CFR 100.120)

JUNE	
Charlie Begin Memorial Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Boothbay Harbor Lobster Boat Race Committee. • Date: June 15, 2013. • Time: 9 a.m. to 3 p.m. • Location: The regulated area includes all waters of Boothbay Harbor, Maine in the vicinity of John's Island within the following points (NAD 83): 43°50′04″ N, 069°38′37″ W. 43°50′54″ N, 069°38′06″ W. 43°50′49″ N, 069°37′50″ W. 43°50′00″ N, 069°38′20″ W.
Rockland Harbor Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Rockland Harbor Lobster Boat Race Committee. • Date: June 16, 2013. • Time: 9 a.m. to 4 p.m. • Location: The regulated area includes all waters of Rockland Harbor, Maine in the vicinity of the Rockland Breakwater Light within the following points (NAD 83): 44°05′59″ N, 069°04′53″ W. 44°06′43″ N, 069°05′25″ W. 44°06′50″ N, 069°05′05″ W. 44°06′05″ N, 069°04′34″ W.
Windjammer Days Parade of Ships	• Event Type: Tall Ship Parade. • Sponsor: Boothbay Region Chamber of Commerce. • Date: June 26, 2013. • Time: 1 p.m. to 5 p.m. • Location: The regulated area includes all waters of Boothbay Harbor, Maine in the vicinity of Tumbler's Island within the following points (NAD 83): 43°51′02″ N, 069°37′33″ W. 43°50′47″ N, 069°37′31″ W. 43°50′23″ N, 069°37′57″ W. 43°50′01″ N, 069°37′45″ W. 43°50′01″ N, 069°38′31″ W. 43°50′25″ N, 069°38′25″ W. 43°50′49″ N, 069°37′45″ W.
JULY	
Searsport Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Searsport Lobster Boat Race Committee. • Date: July 13, 2013. • Time: 9 a.m. to 3 p.m. • Location: The regulated area includes all waters of Searsport Harbor, Maine within the following points (NAD 83): 44°26′50″ N, 068°55′20″ W. 44°27′04″ N, 068°55′26″ W. 44°27′12″ N, 068°54′35″ W. 44°26′59″ N, 068°54′29″ W.
Mayor's Cup Regatta	• Event Type: Sailboat Parade. • Sponsor: Plattsburgh Sunrise Rotary. • Date: July 13, 2013. • Time: 8 a.m. to 5 p.m. • Location: The regulated area includes all waters of Cumberland Bay on Lake Champlain in the vicinity of Plattsburgh, New York within the following points (NAD 83): 44°39′26″ N, 073°26′25″ W. 44°41′27″ N, 073°23′12″ W.
Arthur Martin Memorial Regatta	• Event Type: Rowing and Paddling Boat Race. • Sponsor: International Recreational Open Water Rowing Association. • Date: July 13, 2013. • Time: 9 a.m. to 1 p.m. • Location: The regulated area includes all waters of the Piscataqua River, in the vicinity of Kittery Point, Maine within the following points (NAD 83): 43°03′51″ N, 070°41′55″ W. 43°04′35″ N, 070°42′18″ W. 43°04′42″ N, 070°43′15″ W.

TABLE 1—(33 CFR 100.120)—Continued

	43°05′14″ N, 070°43′12″ W. 43°05′14″ N, 070°43′06″ W. 43°04′44″ N, 070°43′11″ W. 43°04′35″ N, 070°42′13″ W. 43°03′53″ N, 070°41′40″ W.
Stonington Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Stonington Lobster Boat Race Committee. • Date: July 14, 2013. • Time: 9:30 a.m. to 4 p.m. • Location: The regulated area includes all waters of Stonington, Maine within the following points (NAD 83): 44°08′55″ N, 068°40′12″ W. 44°09′00″ N, 068°40′15″ W. 44°09′11″ N, 068°39′42″ W. 44°09′07″ N, 068°39′39″ W.
The Challenge Race	• Event Type: Rowing and Paddling Boat Race. • Sponsor: Lake Champlain Maritime Museum. • Date: July 14, 2013. • Time: 10 a.m. to 3 p.m. • Location: The regulated area includes all waters of Lake Champlain in the vicinity of Button Bay State Park within the following points (NAD 83): 44°12′25″ N, 073°22′32″ W. 44°12′00″ N, 073°21′42″ W. 44°12′19″ N, 073°21′25″ W. 44°13′16″ N, 073°21′36″ W.
Yarmouth Clam Festival Paddle Race	• Event Type: Rowing and Paddling Boat Race. • Sponsor: Maine Island Trail Association. • Date: July 20, 2013. • Time: 8:30 a.m. to 2 p.m. • Location: The regulated area includes all waters in the vicinity of the Royal River outlet and Lane's Island within the following points (NAD 83): 43°47′47″ N, 070°08′40″ W. 43°47′50″ N, 070°07′13″ W. 43°47′06″ N, 070°07′32″ W. 43°47′17″ N, 070°08′25″ W.
Friendship Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Friendship Lobster Boat Race Committee. • Date: July 20, 2013. • Time: 9 a.m. to 3 p.m. • Location: The regulated area includes all waters of Friendship Harbor, Maine within the following points (NAD 83): 43°57′51″ N, 069°20′46″ W. 43°58′14″ N, 069°19′53″ W. 43°58′19″ N, 069°20′01″ W. 43°58′00″ N, 069°20′46″ W.
Harpswell Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Harpswell Lobster Boat Race Committee. • Date: July 28, 2013. • Time: 11 a.m. to 4 p.m. • Location: The regulated area includes waters of Middle Bay near Harpswell, Maine within the following points (NAD 83): 43°44′15″ N, 070°02′06″ W. 43°44′59″ N, 070°01′21″ W. 43°44′51″ N, 070°01′05″ W. 43°44′06″ N, 070°01′49″ W.
Moosabec Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Moosabec Boat Race Committee. • Date: July 29, 2013. • Time: 9 a.m. to 2 p.m. • Location: The regulated area includes all waters of Jonesport, Maine within the following points (NAD 83): 44°31′21″ N, 067°36′44″ W. 44°31′36″ N, 067°36′47″ W. 44°31′44″ N, 067°35′36″ W. 44°31′29″ N, 067°35′33″ W.
AUGUST	
Eggemoggin Reach Regatta	• Event Type: Wooden Boat Parade. • Sponsor: Rockport Marine, Inc. and Brookline Boat Yard. • Date: August 3, 2013. • Time: 11 a.m. to 7 p.m.

TABLE 1—(33 CFR 100.120)—Continued

	• Location: The regulated area includes all waters of Eggemoggin Reach and Jericho Bay in the vicinity of Naskeag Harbor, Maine within the following points (NAD 83): 44°15′16″ N, 068°36′26″ W. 44°12′41″ N, 068°29′26″ W. 44°07′38″ N, 068°31′30″ W. 44°12′54″ N, 068°33′46″ W.
Lake Champlain Dragon Boat Festival	• Event Type: Rowing and Paddling Boat Race. • Sponsor: Dragonheart Vermont. • Date: August 4, 2013. • Time: 7 a.m. to 6 p.m. • Location: The regulated area includes all waters of Burlington Bay within the following points (NAD 83): 44°28′51″ N, 073°13′28″ W. 44°28′40″ N, 073°13′40″ W. 44°28′37″ N, 073°13′29″ W. 44°28′40″ N, 073°13′17″ W.
Southport Rowgatta Rowing and Paddling Boat Race.	• Event Type: Rowing and Paddling Boat Race. • Sponsor: Boothbay Region YMCA. • Date: August 10, 2013. • Time: 8 a.m. to 3 p.m. • Location: The regulated area includes all waters of Sheepscot Bay and Boothbay, on the shore side of Southport Island, Maine within the following points (NAD 83): 43°50′26″ N, 069°39′10″ W. 43°49′10″ N, 069°38′35″ W. 43°46′53″ N, 069°39′06″ W. 43°46′50″ N, 069°39′32″ W. 43°49′07″ N, 069°41′43″ W. 43°50′19″ N, 069°41′14″ W. 43°51′11″ N, 069°40′06″ W.
Winter Harbor Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Winter Harbor Chamber of Commerce. • Date: August 10, 2013. • Time: 9 a.m. to 3 p.m. • Location: The regulated area includes all waters of Winter Harbor, Maine within the following points (NAD 83): 44°22′06″ N, 068°05′13″ W. 44°23′06″ N, 068°05′08″ W. 44°23′04″ N, 068°04′37″ W. 44°22′05″ N, 068°04′44″ W.
Merritt Brackett Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Town of Bristol, Maine. • Date: August 11, 2013. • Time: 10 a.m. to 3 p.m. • Location: The regulated area includes all waters of Pemaquid Harbor, Maine within the following points (NAD 83): 43°52′16″ N, 069°32′10″ W. 43°52′41″ N, 069°31′43″ W. 43°52′35″ N, 069°31′29″ W. 43°52′09″ N, 069°31′56″ W.
Multiple Sclerosis Regatta	• Event Type: Regatta and Sailboat Race. • Sponsor: Maine Chapter, Multiple Sclerosis Society. • Date: August 17, 2013. • Time: 9 a.m. to 3 p.m. • Location: The regulated area for the start of the race includes all waters of Casco Bay, Maine in the vicinity of Peaks Island within the following points (NAD 83): 43°40′24″ N, 070°14′20″ W. 43°40′36″ N, 070°13′56″ W. 43°39′58″ N, 070°13′21″ W. 43°39′46″ N, 070°13′51″ W.
Multiple Sclerosis Harborfest Lobster Boat/Tugboat Races	• Event Type: Power Boat Race. • Sponsor: Maine Chapter, National Multiple Sclerosis Society. • Date: August 18, 2013. • Time: 10 a.m. to 6 p.m. • Location: The regulated area includes all waters of Portland Harbor, Maine in the vicinity of Maine State Pier within the following points (NAD 83): 43°40′25″ N, 070°14′21″ W. 43°40′36″ N, 070°13′56″ W. 43°39′58″ N, 070°13′21″ W. 43°39′47″ N, 070°13′51″ W.

TABLE 1—(33 CFR 100.120)—Continued

SEPTEMBER	
Pirates Festival Lobster Boat Races	• Event Type: Power Boat Race. • Sponsor: Eastport Pirates Festival. • Date: September 8, 2013. • Time: 11 a.m. to 6 p.m. • Location: The regulated area includes all waters in the vicinity of Eastport Harbor, Maine within the following points (NAD 83): 44°54′14″ N, 066°58′52″ W. 44°54′14″ N, 068°58′56″ W. 44°54′24″ N, 066°58′52″ W. 44°54′24″ N, 066°58′56″ W.

TABLE 2—(33 CFR 165.171)

MAY	
Ride Into Summer (formerly listed as Hawgs, Pies, & Fireworks)	• Event Type: Fireworks Display. • Sponsor: Gardiner Maine Street. • Date: May 25, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of the Gardiner Waterfront, Gardiner, Maine in approximate position: 44°13′43″ N, 069°46′04″ W. (NAD 83).
JUNE	
Rotary Waterfront Days Fireworks	• Event Type: Fireworks Display. • Sponsor: Gardiner Rotary. • Date: June 22, 2013. • Time: 8 p.m. to 10 p.m. • Location: In the vicinity of the Gardiner Waterfront, Gardiner, Maine in approximate position: 44°13′52″ N, 069°46′08″ W. (NAD 83).
Windjammer Days Fireworks	• Event Type: Fireworks Display. • Sponsor: Boothbay Harbor Region Chamber of Commerce. • Date: June 26, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of McFarland Island, Boothbay Harbor, Maine in approximate position: 43°50′38″ N, 069°37′57″ W. (NAD 83).
Jonesport 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Jonesport 4th of July Committee. • Date: June 29, 2013. • Time: 8:30 p.m. to 11 p.m. • Location: In the vicinity of Beals Island, Jonesport, Maine in approximate position: 44°31′18″ N, 067°36′43″ W. (NAD 83).
JULY	
Burlington Independence Day Fireworks	• Event Type: Firework Display. • Sponsor: City of Burlington, Vermont. • Date: July 3, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: From a barge in the vicinity of Burlington Harbor, Burlington, Vermont in approximate position: 44°28′31″ N, 073°13′31″ W. (NAD 83).
Camden 4th of July Fireworks (Formerly Camden 3rd of July Fireworks).	• Event Type: Fireworks Display. • Sponsor: Penobscot Bay Regional Chamber of Commerce (Formerly Camden, Rockport, Lincolnville Chamber of Commerce). • Date: July 4, 2013. • Time: 8:15 p.m. to 10:45 p.m. • Location: In the vicinity of Camden Harbor, Maine in approximate position: 44°12′32″ N, 069°02′58″ W. (NAD 83).
Bangor 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Bangor 4th of July Fireworks. • Date: July 4, 2013. • Time: 8:30 p.m. to 11 p.m. • Location: In the vicinity of the Bangor Waterfront, Bangor, Maine in approximate position: 44°47′27″ N, 068°46′31″ W. (NAD 83).

TABLE 2—(33 CFR 165.171)—Continued

Bar Harbor 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Bar Harbor Chamber of Commerce. • Date: July 4, 2013. • Rain date: July 5, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of Bar Harbor Town Pier, Bar Harbor, Maine in approximate position: 44°23′31″ N, 068°12′15″ W. (NAD 83).
Boothbay Harbor 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Boothbay Harbor. • Date: July 4, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of McFarland Island, Boothbay Harbor, Maine in approximate position: 43°50′38″ N, 069°37′57″ W. (NAD 83).
Colchester 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Colchester, Recreation Department. • Date: July 4, 2013. • Rain Date: July 5, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of Bayside Beach and Mallets Bay in Colchester, Vermont in approximate position: 44°32′44″ N, 073°13′10″ W. (NAD 83).
Eastport 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Eastport 4th of July Committee. • Date: July 4, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: From the Waterfront Public Pier in Eastport, Maine in approximate position: 44°54′25″ N, 066°58′55″ W. (NAD 83).
Portland Harbor 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Department of Parks and Recreation, Portland, Maine. • Date: July 4, 2013. • Rain date: July 5, 2013. • Time: 8:30 p.m. to 10:30 p.m. • Location: In the vicinity of East End Beach, Portland, Maine in approximate position: 43°40′16″ N, 070°14′44″ W. (NAD 83).
Stonington 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Deer Isle—Stonington Chamber of Commerce. • Date: July 4, 2013. • Rain Date: July 5, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of Two Bush Island, Stonington, Maine in approximate position: 44°08′57″ N, 068°39′54″ W. (NAD 83).
Ellis Short Sand Park Trustee Fireworks	• Event Type: Fireworks Display. • Sponsor: William Burnham. • Date: July 5, 2013. • Time: 8:30 p.m. to 11:30 p.m. • Location: In the vicinity of York Beach, Maine in approximate position: 43°10′27″ N, 070°36′25″ W. (NAD 83).
Shelburne Sprint Triathlon	• Event Type: Swim Event. • Sponsor: Race Vermont. • Dates: July 6, 2013 and August 3&18, 2013. • Time: 7 a.m. to 10 a.m. • Location: The regulated area includes all waters of Lake Champlain in the vicinity of Shelburne Beach in Shelburne, Vermont within a 400 yard radius of the following point (NAD 83): 44°21′45″ N, 075°15′58″ W.
Vinalhaven 4th of July Fireworks	• Event Type: Firework Display. • Sponsor: Vinalhaven 4th of July Committee. • Date: July 6, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of Grime's Park, Vinalhaven, Maine in approximate position: 44°02′34″ N, 068°50′26″ W. (NAD 83).
Main Street Heritage Days 4th of July Fireworks	• Event Type: Fireworks Display. • Sponsor: Main Street Inc. • Date: July 7, 2013. • Time: 8:15 p.m. to 10:30 p.m. • Location: In the vicinity of Reed and Reed Boat Yard, Woolwich, Maine in approximate position:

TABLE 2—(33 CFR 165.171)—Continued

	43°54′56″ N, 069°48′16″ W. (NAD 83).
St. Albans Day Fireworks	• Event Type: Fireworks Display. • Sponsor: St. Albans Area Chamber of Commerce. • Date: July 9, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: From the St. Albans Bay dock in St. Albans Bay, Vermont in approximate position: 44°48′25″ N 073° 08′23″ W. (NAD 83).
Peaks to Portland Swim	• Event Type: Swim Event. • Sponsor: Cumberland County YMCA. • Date: July 13, 2013. • Time: 9 a.m. to 12 p.m. • Location: The regulated area includes all waters of Portland Harbor between Peaks Island and East End Beach in Portland, Maine within the following points (NAD 83): 43°39′20″ N 070°11′58″ W. 43°39′45″ N 070°13′19″ W. 43°40′11″ N 070°14′13″ W. 43°40′08″ N 070°14′29″ W. 43°40′00″ N 070°14′23″ W. 43°39′34″ N 070°13′31″ W. 43°39′13″ N 070°11′59″ W.
St. George Days Fireworks	• Event Type: Fireworks. • Sponsor: Town of St. George. • Date: July 20, 2013. • Time: 8:30 p.m. to 10:30 p.m. • Location: The regulated area includes all waters of Inner Tenants Harbor, ME, in approximate position (NAD 83): 43°57′41.37″ N, 069°12′45″ W.
Richmond Days Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Richmond, Maine. • Date: July 27, 2013. • Time: 9:15 p.m. to 9:30 p.m. • Location: From a barge in the vicinity of the inner harbor, Tenants Harbor, Maine in approximate position: 44°08′42″ N, 068°27′06″ W. (NAD83).
Friendship Days Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Friendship. • Date: July 27, 2013. • Time: 9 p.m. to 9:30 p.m. • Location: In the vicinity of the Town Pier, Friendship Harbor, Maine in approximate position: 43°58′23″ N, 069°20′12″ W. (NAD83).
Bucksport Festival and Fireworks	• Event Type: Fireworks Display. • Sponsor: Bucksport Bay Area Chamber of Commerce. • Date: July 27, 2013. • Time: 9:15 p.m. to 10 p.m. • Location: In the vicinity of the Verona Island Boat Ramp, Verona, Maine, in approximate position: 44°34′9″ N, 068°47′28″ W (NAD83).
Colchester Triathlon	• Event Type: Swim Event. • Sponsor: Colchester Parks and Recreation Department. • Date: July 28, 2013. • Time: 9 a.m. to 9:45 a.m. • Location: The regulated area includes all waters of Malletts Bay on Lake Champlain, Vermont within the following points (NAD 83): 44°32′18″ N 073°12′35″ W. 44°32′28″ N 073°12′56″ W. 44°32′57″ N 073°12′38″ W.
AUGUST	
Sprucewold Cabbage Island Swim	• Event Type: Swim Event. • Sponsor: Sprucewold Association. • Date: August 10, 2013. • Time: 1 p.m. to 6 p.m. • Location: The regulated area includes all waters of Linekin Bay between Cabbage Island and Sprucewold Beach in Boothbay Harbor, Maine within the following points (NAD 83): 43°50′37″ N 069°36′23″ W. 43°50′37″ N 069°36′59″ W. 43°50′16″ N 069°36′46″ W. 43°50′22″ N 069°36′21″ W.
Westerlund's Landing Party Fireworks	• Event Type: Fireworks Display.

TABLE 2—(33 CFR 165.171)—Continued

	• Sponsor: Portside Marina. • Date: August 3, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of Westerlund's Landing in South Gardiner, Maine in approximate position: 44°10′19″ N, 069°45′24″ W. (NAD 83).
Y-Tri Triathlon	• Event Type: Swim Event. • Sponsor: Plattsburgh YMCA. • Date: August 3, 2013. • Time: 8:30 a.m. to 10 a.m. • Location: The regulated area includes all waters of Treadwell Bay on Lake Champlain in the vicinity of Point Au Roche State Park, Plattsburgh, New York within the following points (NAD 83): 44°46′30″ N 073°23′26″ W. 44°46′17″ N 073°23′26″ W. 44°46′17″ N 073°23′46″ W. 44°46′29″ N 073°23′46″ W.
York Beach Fire Department Fireworks	• Event Type: Fireworks Display. • Sponsor: York Beach Fire Department. • Date: August 4, 2013. • Time: 8:30 p.m. to 11:30 p.m. • Location: In the vicinity of Short Sand Cove in York, Maine in approximate position: 43°10′27″ N, 070°36′25″ W. (NAD 83).
Rockland Breakwater Swim	• Event Type: Swim Event. • Sponsor: Pen-Bay Masters. • Date: August 31, 2013. • Time: 7:30 a.m. to 1:30 p.m. • Location: The regulated area includes all waters of Rockland Harbor, Maine in the vicinity of Jameson Point within the following points (NAD 83): 44°06′16″ N 069°04′39″ W. 44°06′13″ N 069°04′36″ W. 44°06′12″ N 069°04′43″ W. 44°06′17″ N 069°04′44″ W. 44°06′18″ N 069°04′40″ W.
Tri for Preservation	• Event Type: Swim Event. • Sponsor: Tri-Maine Productions. • Date: August 18, 2013. • Time: 6:30 a.m. to 10 a.m. • Location: In the vicinity of Crescent Beach State Park in Cape Elizabeth, Maine in approximate position: 43°33′46″ N 070°13′48″ W. 43°33′41″ N 070°13′46″ W. 43°33′44″ N 070°13′40″ W. 43°33′47″ N 070°13′46″ W.
Windjammer Weekend Fireworks	• Event Type: Fireworks Display. • Sponsor: Town of Camden, Maine. • Date: August 30, 2013. • Rain date: September 1, 2013. • Time: 8 p.m. to 9:30 p.m. • Location: From a barge in the vicinity of Northeast Point, Camden Harbor, Maine in approximate position: 44°12′10″ N, 069°03′11″ W. (NAD 83).
SEPTEMBER	
Eastport Pirate Festival Fireworks	• Event Type: Fireworks Display. • Sponsor: Eastport Pirate Festival. • Date: September 7, 2013. • Time: 7 p.m. to 10:00 p.m. • Location: From the Waterfront Public Pier in Eastport, Maine in approximate position: 44°54′17″ N, 066°58′58″ W. (NAD 83).
The Lobsterman Triathlon	• Event Type: Swim Event. • Sponsor: Tri-Maine Productions. • Date: September 14, 2013. • Time: 7 a.m. to 11:00 a.m. • Location: The regulated area includes all waters in the vicinity of Winslow Park in South Freeport, Maine within the following points (NAD 83): 43°47′59″ N 070°06′56″ W. 43°47′44″ N 070°06′56″ W.

TABLE 2—(33 CFR 165.171)—Continued

Eliot Festival Day Fireworks	43°47′44″ N 070°07′27″ W. 43°47′57″ N 070°07′27″ W. • Event Type: Fireworks Display. • Sponsor: Eliot Festival Day Committee. • Date: September 27, 2013. • Rain date: September 29, 2013. • Time: 8 p.m. to 10:30 p.m. • Location: In the vicinity of Eliot Town Boat Launch, Eliot, Maine in approximate position: 43°08′56″ N, 070°49′52″ W. (NAD 83).

For events where the date is different from the dates previously published for that event, new Temporary Rules may be issued to enforce limited access areas for the marine event. The Coast Guard may patrol each event area under the direction of a designated Coast Guard Patrol Commander. The Patrol Commander may be contacted on Channel 16 VHF–FM (156.8 MHz) by the call sign ''PATCOM.'' Official patrol vessels may consist of any Coast Guard, Coast Guard Auxiliary, state, or local law enforcement vessels assigned or approved by the Captain of the Port, Sector Northern New England. For information about regulations and restrictions for waterway use during the effective periods of these events, please refer to 33 CFR 100.120 and 33 CFR 165.171.

This notice is issued under authority of 33 CFR 100.120, 33 CFR 165.171, and 5 U.S.C. 552 (a). In addition to this notice in the **Federal Register**, the Coast Guard will provide the maritime community with advance notification of this enforcement period via the Local Notice to Mariners and marine information broadcasts. If the COTP determines that the regulated area need not be enforced for the full duration stated in this notice, he or she may use a Broadcast Notice to Mariners to grant general permission to enter the regulated area.

Dated: May 24, 2013.

B.S. Gilda,

Captain, U. S. Coast Guard, Captain of the Port Sector Northern New England.

[FR Doc. 2013–13907 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0921; FRL–9386–8]

1,3-Propanediol; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of 1,3-propanediol (CAS Reg. No. 504–63–2) when used as an inert ingredient solvent, co-solvent, diluent, or freeze-point depressant in pesticide formulations applied to growing crops and to raw agricultural crops after harvest and in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. DuPont Tate & Lyle BioProducts submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of exemptions from the requirement of a tolerance. These regulations eliminate the need to establish a maximum permissible level for residues of 1,3-propanediol.

DATES: This regulation is effective June 12, 2013. Objections and requests for hearings must be received on or before August 12, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0921, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: David Lieu, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–0079; email address: *lieu.david@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select ''Test Methods and Guidelines.''

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2012–0921 in the subject line on

the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 12, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0921, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of January 16, 2013 (78 FR 3377) (FRL–9375–4), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP 2E8091) by DuPont Tate & Lyle BioProducts, LLC, 198 Blair Bend Dr., Loudon, TN 37774. The petition requested two exemptions from the requirement of a tolerance be established for residues of 1,3-propanediol (CAS Reg. No. 504–63–2) when used as an inert ingredient under 40 CFR 180.910 for its use as a solvent, co-solvent, diluent, or freeze-point depressant in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and under 40 CFR 180.940(a) for its use in antimicrobial pesticide formulations applied to food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. That document referenced a summary of the petition prepared by DuPont Tate & Lyle BioProducts, the petitioner, which is available in the docket, *http://www.regulations.gov.* There were no comments received in response to the notice of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply non-toxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 1,3-propanediol including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with 1,3-propanediol follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by 1,3-propanediol as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The acute oral toxicity of 1,3-propanediol in rodents, expressed as an LD_{50} ranges from 10,500 to 15,789 milligram/kilogram body weight (mg/kg bw). No acute dermal toxicity studies for 1,3-propanediol were available in the toxicity database. The acute inhalation toxicity of 1,3-propanediol in rats produced a LC_{50} was > 5.0 mg/liter (L). It is minimally irritating to the eyes of rabbits. It is mildly irritating to the skin of rabbits. Dermal sensitization studies on guinea pigs showed that 1,3-propanediol is not a sensitizer.

In a 14-day inhalation toxicity study, three groups of 10 male Crl:CD (SD) IGS BR rats each were exposed by inhalation to either vapor only or a vapor/aerosol mixture of 1,3-propanediol in air at concentrations targeted to 60, 600, or 1,800 mg/meter cubed (m^3) (0.06, 0.60,

or 1.80 mg/L) for 6 hours/day, 4 or 5 days/week for a total of 9 exposures. A procedural control group of 10 male rats were exposed simultaneously to air only. There were no clinical signs of toxicity, body weight effects, clinical chemistry parameters, hematology measurements, and histopathological findings. The NOAEL for repeated inhalation exposure to 1,3-propanediol in male rats was considered to be 1,800 mg/m^3 or 1.8 mg/L (the highest dose tested) and no LOAEL was identified.

In a 90-day oral toxicity study, 1,3-propanediol was administered to 10 Crl:CD®(SD)BR rats/sex/dose by gavage at dosages of 0, 100, 300, or 1,000 mg/kg/day. No treatment-related effects were observed on clinical signs, mortality, body weights and body weight gain, food consumption, ophthalmoscopic examination, sperm abnormalities, organ weights and macroscopic, and microscopic examinations at doses up to and including 1,000 mg/kg/day. The NOAEL for systemic toxicity of 1,3-propanediol administered orally via gavage to male and female rats for 91 or 92 consecutive days was 1,000 mg/kg/day (the highest dose tested) and no LOAEL was identified.

The mutagenic potential of 1,3-propanediol was evaluated in a bacterial reverse mutation test, an *in vitro* mammalian cell gene mutation test, an *in vitro* chromosome aberration assay, an *in vitro* mammalian cell chromosome aberration assay, and an *in vivo* mammalian erythrocyte micronucleus test. Although the *in vitro* mammalian cell chromosome aberration assay in the V79 Chinese hamster cell line indicated some chromosomal aberrations, the remainders of the studies including the *in vivo* mouse micronucleus assay were negative; therefore, there are no concerns for clastogenicity. Based on the results of these studies, 1,3-propanediol is not considered to be mutagenic.

No carcinogenicity studies on 1,3-propanediol were available in the toxicity database, however based on the lack of mutagenicity concerns, lack of any systemic toxicity at the limit dose, and lack of any structural alerts for carcinogenicity in the Derek analysis, there are no concerns for carcinogenicity for 1,3-propanediol.

In a developmental toxicity study, 1,3-propanediol was administered to 20 pregnant female Sprague-Dawley (Hag:SD) rats/dose by gavage in 0.8% aqueous hydroxypropyl-methylcellulose gel (with constant dose volume of 10 milliliter (mL)/kg bw) at dose levels of 0, 250, or 1,000 mg/kg bw/day on gestation days (GDs) 6 through 15. Dams were sacrificed and necropsied on gestation day (GD) 20. There were no treatment-related effects on maternal survival, clinical signs, body weight, food consumption, or gross pathology. The maternal LOAEL is not identified, and the maternal NOAEL is greater than or equal to 1,000 mg/kg bw/day (the highest dose tested). There were no treatment-related effects on live litter size, fetal deaths, fetal weights, early or late resorptions, or the fetal sex ratio. The developmental LOAEL is not identified, and the developmental NOAEL is greater than or equal to 1,000 mg/kg bw/day (the highest dose tested).

There were no immunotoxicity or neurotoxicity studies on 1,3-propanediol available in the toxicity database. However, there was no evidence of clinical signs of neurotoxicity or immunotoxicity triggers in the available database up to the limit dose.

The proposed metabolic pathway for 1,3-propanediol follows that for other simple alcohols, where alcohol and aldehyde dehydrogenase enzymes sequentially break down this substance to aldehydes and acids used in intermediary metabolism. 1,3-propanediol is metabolized to 3-hydroxypropionaldehyde, malondialdehyde, or 3-hydroxypropionic acid, malonic semi-aldehyde, malonic acid, and ultimately, carbon dioxide and water.

B. Toxicological Points of Departure/ Levels of Concern

There was no hazard identified in repeat dose toxicity and developmental studies with 1,3-propanediol at the limit dose of 1,000 mg/kg/day to either parental animals or their offspring. Based on the available mutagenicity studies, EPA concluded that 1,3-propanediol is not likely to be genotoxic. In addition, there were no structural alerts for carcinogenicity in the Derek analysis. Thus, due to its low potential hazard and lack of hazard endpoint, the Agency has determined that a quantitative risk assessment using safety factors applied to a point of departure protective of an identified hazard endpoint is not appropriate for 1,3-propanediol.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to 1,3-propanediol, EPA considered exposure under the proposed exemptions from the requirement of a tolerance. Dietary exposure to 1,3-propanediol can occur eating food treated with pesticide formulation containing this inert ingredient. In addition, dietary exposure to 1,3-propanediol could occur via residues from treated food contact surfaces. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment for 1,3-propanediol was not conducted.

2. *Dietary exposure from drinking water.* Dietary exposure from drinking water to 1,3-propanediol can occur by drinking water that has been contaminated by run-off from a pesticide treated area and from antimicrobial formulations used in food-contact surface sanitizing solutions. Since an endpoint for risk assessment was not identified, a quantitative dietary exposure assessment from drinking water for 1,3-propanediol was not conducted.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, and tables).

Residential (oral, dermal, and inhalation) exposure from food-contact surface sanitizing solutions for public eating places, dairy-processing equipment, and food-processing equipment and utensils are possible. In addition, residential exposure through other potential agricultural uses is also possible. Since an endpoint for risk assessment was not identified, a quantitative residential exposure assessment for 1,3-propanediol was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found 1,3-propanediol to share a common mechanism of toxicity with any other substances, and 1,3-propanediol does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that 1,3-propanediol does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at

http://www.epa.gov/pesticides/cumulative.

D. Safety Factor for Infants and Children

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. The toxicity database for 1,3-propanediol contains several acute and subchronic studies, mutagenic studies, and a developmental toxicity study. No hazard was identified based on those studies. The toxicity database does not contain a carcinogenicity study and an immunotoxicity study, but for the reasons stated in Unit IV.A., the Agency has concluded that there are no concerns for carcinogenicity or immunotoxicity for this chemical. No acute or subchronic neurotoxicity studies are available, but there were no clinical signs of neurotoxicity or any systemic toxicity observed with 1,3-propanediol in the available database at doses up to 1,000 mg/kg/day. No developmental or reproductive effects were seen in the available studies at doses of 1,3-propanediol up to and including 1,000 mg/kg/day. Thus, there is no residual uncertainty regarding prenatal and/or postnatal toxicity of 1,3-propanediol.

Based on this information, there is no concern at this time for increased sensitivity to infants and children to 1,3-propanediol when used as an inert ingredient in pesticide formulations applied to growing crops, raw agricultural commodities after harvest, and for food-contact surface sanitizing applications.

E. Aggregate Risks and Determination of Safety

Taking into consideration all available information on 1,3-propanediol, EPA has determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to 1,3-propanediol under reasonable foreseeable circumstances. Therefore, the establishment of exemptions from tolerance under 40 CFR 180.910 for residues of 1,3-propanediol when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and under 40 CFR 180.940(a) for residues of 1,3-propanediol when used as an inert ingredient in food-contact surface sanitizing solutions for public eating places, dairy-processing equipment, and food-processing equipment and utensils is safe under FFDCA section 408.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single-oral exposure was identified and no acute dietary endpoint was selected. Therefore, 1,3-propanediol is not expected to pose an acute risk.

2. *Chronic risk.* A chronic aggregate risk assessment takes into account chronic exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a chronic oral exposure was identified, and no chronic dietary endpoint was selected. Therefore, 1,3-propanediol is not expected to pose a chronic risk.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term adverse effect was identified, 1,3-propanediol is not expected to pose a short-term risk.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term adverse effect was identified, 1,3-propanediol is not expected to pose a intermediate-term risk.

5. *Aggregate cancer risk for U.S. population.* As discussed in Unit IV.A., 1,3-propanediol is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to 1,3-propanediol residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing exemptions from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nation Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for 1,3-propanediol.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of 1,3-propanediol (CAS Reg. No. 504–63–2) under 40 CFR 180.910 when used as an inert ingredient (solvent, co-solvent, diluent, or freeze point depressant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest and under 40 CFR 180.940(a) when used as an inert ingredient in food-contact surface sanitizing solutions for public eating places, dairy-processing equipment, and food-processing equipment and utensils.

VII. Statutory and Executive Order Reviews

This final rule establishes exemptions from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as

the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 3, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, add to the table, after the entry ''Propane,'' the following inert ingredient to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

Inert ingredients	Limits	Uses
* * * * * * *		
1,3-Propanediol (CAS Reg. No. 504–63–2)	.....	Solvent, co-solvent, diluent, or freeze-point depressant.
* * * * * * *		

■ 3. In § 180.940, add to the table in paragraph (a), after the entry ''potassium iodide,'' the following inert ingredient to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

(a) * * *

* * * * *

Pesticide chemical	CAS Reg. No.	Limits
* * * * * * *		
1,3-Propanediol	504–63–2	None.
* * * * * * *		

* * * * *

[FR Doc. 2013–13823 Filed 6–11–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012–0264; FRL–9389–2]

Bacillus pumilus Strain BU F–33; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of *Bacillus pumilus* strain BU F–33 in or on all food commodities when applied to elicit induced systemic resistance in plants and used in accordance with label directions and good agricultural practices. Becker Underwood, Inc., submitted a petition to the EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus pumilus* strain BU F–33 under the FFDCA.

DATES: This regulation is effective June 12, 2013. Objections and requests for hearings must be received on or before August 12, 2013, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2012–0264, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency

Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT:

Jeannine Kausch, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 347–8920; email address: *kausch.jeannine@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl*.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by the EPA, you must identify docket ID number EPA–HQ–OPP–2012–0264 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before August 12, 2013. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by the EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2012–0264, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background

In the **Federal Register** of September 28, 2012 (77 FR 59578) (FRL–9364–6), the EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 2F7978) by Becker Underwood, Inc., 801 Dayton Ave., P.O. Box 667, Ames, IA 50010. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus pumilus* strain BU F–33. The notice referenced a summary of the petition prepared by the petitioner, Becker Underwood, Inc., which is available in the docket via *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

III. Final Rule

A. The EPA's Safety Determination

Section 408(c)(2)(A)(i) of FFDCA allows the EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if the EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, the EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require the EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance exemption and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .'' Additionally, FFDCA section 408(b)(2)(D) requires that the EPA consider ''available information concerning the cumulative effects of [a particular pesticide's] . . . residues and other substances that have a common mechanism of toxicity.''

The EPA evaluated the available toxicity and exposure data on *Bacillus pumilus* strain BU F–33 and considered its validity, completeness, and reliability, as well as the relationship of this information to human risk. Based upon that evaluation, the EPA concludes that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Bacillus pumilus* strain BU F–33. Therefore, an exemption from the requirement of a tolerance is established for residues of *Bacillus pumilus* strain BU F–33 in or on all food commodities when applied to elicit induced systemic resistance in plants and used in accordance with label directions and good agricultural practices. A full explanation of the data upon which the EPA relied and its risk assessment based on that data can be found within the May 22, 2013 document entitled ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Bacillus pumilus* strain BU F–33.'' This document, as well as other relevant information, is available in the docket

for this action as described under **ADDRESSES.**

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes for the reasons stated above and in the document entitled ''Federal Food, Drug, and Cosmetic Act (FFDCA) Considerations for *Bacillus pumilus* strain BU F–33,'' and because the EPA is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. International Residue Limits

In making its tolerance decisions, the EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. In this context, the EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. The EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that the EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for *Bacillus pumilus* strain BU F–33.

IV. Statutory and Executive Order Reviews

This final rule establishes a tolerance exemption under FFDCA section 408(d) in response to a petition submitted to the EPA. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes. As a result, this action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the EPA determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the EPA determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require the EPA's consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 31, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Add § 180.1322 to subpart D to read as follows:

§ 180.1322 *Bacillus pumilus* strain BU F–33; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Bacillus pumilus* strain BU F–33 in or on all food commodities when applied to elicit induced systemic resistance in plants and used in accordance with label directions and good agricultural practices.

[FR Doc. 2013–13821 Filed 6–11–13; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Parts 2, 10, 13, 15, 21, 29, 80, 84, 85, and 100

[Docket No. FWS–HQ–BPHR–2012–0089; FXGO16600954000–134–FF09B30000]

RIN 1018–AY13

Addresses of Regional Offices

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), are updating the names and addresses of our regional offices in our regulations at title 50 of the Code of Federal Regulations. We are also making other revisions to our regulations, such as updating the names and phone numbers of certain other Service offices. We are taking these actions to ensure regulated entities and the general public have accurate contact information for the Service's offices.

DATES: This rule is effective June 12, 2013.

ADDRESSES: This final rule is available on the Internet at *http://www.regulations.gov* under Docket No. FWS–HQ–BPHR–2012–0089.

FOR FURTHER INFORMATION CONTACT: Andrew Brown, 703–358–2179.

SUPPLEMENTARY INFORMATION: Section 2.2 of the regulations in title 50 of the Code of Federal Regulations (CFR) provides the names, geographic jurisdictions, and addresses of the Service's regional offices. Before publication of this rule, the names, geographic jurisdictions, and addresses of our regional offices had not been updated since 1998. This final rule updates the names and addresses of the regional offices for our Regions 1 through 7; removes California and Nevada from the geographic jurisdiction of our Region 1; and provides the name, geographic jurisdiction (California and Nevada), and address for our Region 8.

This final rule also revises regulations at 50 CFR parts 10, 13, 21, 29, 84, 85, and 100 that duplicate regional office addresses. To increase efficiency, reduce redundancy, and ensure that all information is accurate and up-to-date, we are removing duplicate addresses for our regional offices throughout our regulations. Instead, we refer the reader to 50 CFR 2.2 for the addresses of our regional offices. These revisions also include, where applicable, adding updated contact information, such as telephone and fax numbers, for Service offices. See the Regulation Promulgation section of this rule for the specific revisions we are making to these regulations.

Additionally, this final rule revises regulations at 50 CFR parts 84 and 85 that included an outdated name of a Service division. To provide accurate contact information, we are removing references to the ''Division of Federal Aid,'' and replacing them with the current name of the program: Wildlife and Sport Fish Restoration. As well, this final rule revises regulations at 50 CFR parts 80, 84, and 85 that include an outdated name for the Service's Arlington office. We are removing references to the ''Washington Office,'' and replacing them with the up-to-date name of the office: Headquarters. See the Regulation Promulgation section of this rule for the specific revisions we are making to these regulations.

Finally, we are correcting the authority citation for 50 CFR part 15 and revising, to reduce redundancy and correct sequence, the authority citations for 50 CFR parts 10, 21, and 29.

These actions are administrative in nature. We are providing regulated entities and the general public with accurate contact information for the Service's offices. Under 5 U.S.C. 553(b), rules of agency organization, procedure, or practice may be made final without previous notice to the public. This is a final rule. In addition, under 5 U.S.C. 553(d), we may make this rule effective in less than 30 days if we have ''good cause'' to do so. The rule provides accurate contact information for our offices, and this action will benefit regulated entities and the general public. Therefore, we find that we have ''good cause'' to make this rule effective immediately.

Required Determinations

Regulatory Planning and Review—Executive Orders 12866 and 13563

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Regulatory Flexibility Act (5 U.S.C. 601 et seq.)

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.,* as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996 (Pub. L. 104–121)), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (that is, small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities.

SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide the statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

We have examined this rule's potential effects on small entities as required by the Regulatory Flexibility Act, and have determined that this action will not have a significant economic impact on a substantial number of small entities. This rule updates the contact information for our offices in our regulations in Title 50 of the Code of Federal Regulations. We are taking this action to ensure that regulated entities and the general public have accurate contact information for the Service's offices. This rule will not result in any costs or benefits to any entities, large or small.

Therefore, we certify that, because this rule will not have a significant economic effect on a substantial number of small entities, a regulatory flexibility analysis is not required.

This rule is not a major rule under the SBREFA (5 U.S.C. 804(2)). It will not have a significant economic impact on a substantial number of small entities.

a. This rule does not have an annual effect on the economy of $100 million or more. There are no costs to any entities resulting from these revisions to the regulations.

b. This rule will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions. The updating of the Service's contact information does not affect costs or prices in any sector of the economy.

c. This rule will not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we have determined the following:

a. This rule will not ''significantly or uniquely'' affect small governments in a negative way. A small government agency plan is not required.

b. This rule will not produce a Federal mandate of $100 million or greater in any year. It is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Takings

Under the criteria outlined in E.O. 12630, this final rule does not have significant takings implications. This rule does not contain a provision for taking of private property. A takings implication assessment is not required.

Federalism

This rule does not have sufficient Federalism effects to warrant preparation of a federalism summary impact statement under E.O. 13132.

Civil Justice Reform

In accordance with E.O. 12988, the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

Paperwork Reduction Act

This rule does not contain any information collection that would require approval under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

National Environmental Policy Act

We evaluated the environmental impacts of the changes to the regulations, and determined that this rule does not have any environmental impacts.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations With Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and 512 DM 2, we have evaluated potential effects on Federally recognized Indian Tribes and have determined that this rule will not interfere with Tribes' ability to manage themselves or their funds. This rule offers Tribes and the general public accurate contact information for our offices.

Energy Supply, Distribution, or Use

E.O. 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Because this rule is administrative, it is not a significant regulatory action under E.O. 12866, and it will not significantly affect energy supplies, distribution, or use. Therefore, this action is not a significant energy action and no Statement of Energy Effects is required.

List of Subjects

50 CFR Part 2

Organization and functions (Government agencies).

50 CFR Part 10

Exports, Fish, Imports, Law enforcement, Plants, Transportation, Wildlife.

50 CFR Part 13

Administrative practice and procedure, Exports, Fish, Imports, Plants, Reporting and recordkeeping requirements, Transportation, Wildlife.

50 CFR Part 15

Imports, Reporting and recordkeeping requirements, Wildlife.

50 CFR Part 21

Exports, Hunting, Imports, Reporting and recordkeeping requirements, Transportation, Wildlife.

50 CFR Part 29

Public lands—mineral resources, Public lands—rights-of-way, Wildlife refuges.

50 CFR Part 80

Fish, Grant programs—natural resources, Reporting and recordkeeping requirements, Signs and symbols, Wildlife.

50 CFR Part 84

Coastal zone, Environmental protection, Grant programs—natural resources, Intergovernmental relations, Marine resources, Reporting and recordkeeping requirements, Wildlife.

50 CFR Part 85

Coastal zone, Grant programs—natural resources, Reporting and recordkeeping requirements, Sewage disposal, Vessels.

50 CFR Part 100

Administrative practice and procedure, Alaska, Fish, National forests, Public lands, Reporting and recordkeeping requirements, Wildlife.

Regulation Promulgation

Accordingly, we amend parts 2, 10, 13, 15, 21, 29, 80, 84, 85, and 100 of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 2—FIELD ORGANIZATION

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 5 U.S.C. 301.

■ 2. Revise § 2.2 to read as follows:

§ 2.2 Locations of regional offices.

The geographic jurisdictions and addresses of the U.S. Fish and Wildlife regional offices are as follows:

(a) Pacific Regional Office (Region 1—comprising the States of Hawaii, Idaho, Oregon, and Washington; the Commonwealth of the Northern Mariana Islands; and American Samoa, Guam, and other Pacific possessions), Eastside Federal Complex, 911 NE. 11th Avenue, Portland, Oregon 97232.

(b) Southwest Regional Office (Region 2—comprising the States of Arizona, New Mexico, Oklahoma, and Texas), 500 Gold Avenue SW., Room 9018 (P.O. Box 1306), Albuquerque, New Mexico 87102.

(c) Midwest Regional Office (Region 3—comprising the States of Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, and Wisconsin), 5600 American Boulevard West, Suite 990, Bloomington, Minnesota 55437.

(d) Southeast Regional Office (Region 4—comprising the States of Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee; the Commonwealth of Puerto Rico; and the Virgin Islands and Caribbean possessions), 1875 Century Boulevard, Suite 400, Atlanta, Georgia 30345.

(e) Northeast Regional Office (Region 5—comprising the States of Connecticut, Delaware, Maine, Maryland, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont, Virginia, and West Virginia; and the District of Columbia), 300 Westgate Center Drive, Hadley, Massachusetts 01035.

(f) Mountain-Prairie Regional Office (Region 6—comprising the States of Colorado, Kansas, Montana, Nebraska, North Dakota, South Dakota, Utah and Wyoming), 134 Union Boulevard (P.O. Box 25486), Lakewood, Colorado 80228.

(g) Alaska Regional Office (Region 7—comprising the State of Alaska), 1011 E. Tudor Road, Anchorage, Alaska 99503.

(h) Pacific Southwest Regional Office (Region 8—comprising the States of California and Nevada), 2800 Cottage Way, Room W–2606, Sacramento, California 95825.

PART 10—GENERAL PROVISIONS

■ 3. Revise the authority citation for part 10 to read as follows:

Authority: 16 U.S.C. 668a–d, 703–712, 742a–j–l, 1361–1384, 1401–1407, 1531–1543, 3371–3378; 18 U.S.C. 42; 19 U.S.C. 1202.

■ 4. Revise § 10.22 to read as follows:

§ 10.22 Law enforcement offices.

(a) Service law enforcement offices are located in Service regional offices. Regional office addresses are provided at 50 CFR 2.2. Mail should be addressed to ''Special Agent in Charge, Office of Law Enforcement, U.S. Fish and Wildlife Service'' at the appropriate

regional office address. Telephone numbers for Service law enforcement offices follow:

Region	Law enforcement office telephone number
1	503–231–6125
2	505–248–7889
3	612–713–5320
4	404–679–7057
5	413–253–8274
6	303–236–7540
7	907–786–3311
8	916–414–6660

(b) Any foreign country should contact the Service's Headquarters Law Enforcement Office at: Office of Law Enforcement, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, MS: LE–3000, Arlington, VA 22203–3247; Telephone: 703–358–1949.

PART 13—GENERAL PERMIT PROCEDURES

■ 5. The authority citation for part 13 continues to read as follows:

Authority: 16 U.S.C. 668a, 704, 712, 742j–l, 1374(g), 1382, 1538(d), 1539, 1540(f), 3374, 4901–4916; 18 U.S.C. 42; 19 U.S.C. 1202; 31 U.S.C. 9701.

■ 6. Amend § 13.11 by revising paragraph (b)(5) to read as follows:

§ 13.11 Application procedures.

* * * * *

(b) * * *

(5) You may obtain applications for bald and golden eagle permits (50 CFR part 22) and migratory bird permits (50 CFR part 21), except for banding and marking permits, from, and you may submit completed applications to, the ''Migratory Bird Permit Program Office'' in the Region in which you reside. For addresses of the regional offices, see 50 CFR 2.2, or go to: *http://www.fws.gov/migratorybirds/mbpermits/Addresses.html.*

* * * * *

PART 15—WILD BIRD CONSERVATION ACT

■ 7. Revise the authority citation for part 15 to read as follows:

Authority: 16 U.S.C. 4901–4916.

PART 21—MIGRATORY BIRD PERMITS

■ 8. Revise the authority citation for part 21 to read as follows:

Authority: 16 U.S.C. 703–712.

■ 9. Amend § 21.29 by revising paragraph (e)(3)(ii)(E) to read as follows:

§ 21.29 Falconry standards and falconry permitting.

* * * * *

(e) * * *

(3) * * *

(ii) * * *

(E) Before you begin any trapping activities, you must inform our regional Law Enforcement office of your capture plans. You must notify the office in person, in writing, or via facsimile or email at least 3 business days before you start trapping. You may send an email with your trapping plans to *lawenforcement@fws.gov,* or you may deliver your trapping plans in person or by mail to the Law Enforcement office in your region at the applicable street address provided at 50 CFR 2.2. Telephone and fax numbers are as follows:

Region	Law enforcement office telephone number	Law enforcement office fax number
1	503–231–6125	503–231–2193
2	505–248–7889	505–248–7899
3	612–713–5320	612–713–5283
4	404–679–7057	404–679–7065
5	413–253–8274	413–253–8459
6	303–236–7540	303–236–7901
7	907–786–3311	907–786–3313
8	916–414–6660	916–414–6715

* * * * *

PART 29—LAND USE MANAGEMENT

■ 10. Revise the authority citation for part 29 to read as follows:

Authority: Sec. 2, 33 Stat. 614, as amended, sec. 5, 43 Stat. 651, secs. 5, 10, 45 Stat. 449, 1224, secs. 4, 2, 48 Stat. 402, as amended, 1270, sec. 4, 76 Stat. 645, 80 Stat. 926; 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd, 685, 690d, 715i, 725; 43 U.S.C. 315a.

■ 11. Amend § 29.21–2 by:

■ a. Revising paragraph (a)(1) to read as set forth below; and

■ b. By removing paragraph (c).

§ 29.21–2 Application procedures.

(a) * * *

(1) No special form of application is required. The application should state the purpose for which the right-of-way is being requested together with the length, width on each side of the centerline, and the estimated acreage. Applications, including exhibits, must be filed in triplicate with the Regional Director for the region in which the State is located. A list of States in each region and the addresses of the regional offices are provided at 50 CFR 2.2.

* * * * *

PART 80—ADMINISTRATIVE REQUIREMENTS, PITTMAN-ROBERTSON WILDLIFE RESTORATION AND DINGELL-JOHNSON SPORT FISH RESTORATION ACTS

■ 12. The authority citation for part 80 continues to read as follows:

Authority: 16 U.S.C. 669–669k; 16 U.S.C. 777–777n, except 777e–1 and g–1.

§ 80.2 [Amended]

■ 13. Amend § 80.2, in the definition of *Regional Director,* by removing the words ''Washington Office'' and by adding, in their place, the word ''Headquarters''.

PART 84—NATIONAL COASTAL WETLANDS CONSERVATION GRANT PROGRAM

■ 14. The authority citation for part 84 continues to read as follows:

Authority: 16 U.S.C. 3951–3956.

■ 15. Amend § 84.21 by:

■ a. Amending paragraph (a)(1) by removing the words ''Service Regional Federal Aid Offices''' and by adding, in their place, the words ''Service Regional Wildlife and Sport Fish Restoration Offices''';

■ b. Amending paragraph (a)(2) by removing the words ''Federal Aid'' and by adding, in their place, the words ''Wildlife and Sport Fish Restoration'';

■ c. Revising paragraph (a)(3) to read as set forth below; and

■ d. Amending paragraph (b) by removing the words ''Regional Federal Aid Offices'' and by adding, in their place, the words ''Regional Wildlife and Sport Fish Restoration Offices''.

§ 84.21 How do I apply for a National Coastal Wetlands Conservation Grant?

(a) * * *

(3) Send your proposal to ''Regional Director (Attention: Wildlife and Sport Fish Restoration)'' at the address of the appropriate regional office, as provided at 50 CFR 2.2.

* * * * *

§ 84.30 [Amended]

■ 16. Amend § 84.30:

■ a. By amending paragraph (a)(1) by:

■ i. Removing the words ''The Regional Federal Aid Offices'' and by adding, in their place, the words ''The Regional Wildlife and Sport Fish Restoration Offices''; and

■ ii. Removing the words ''the Washington Office'' and by adding, in their place, the word ''Headquarters''; and

■ b. By amending paragraph (b) by removing the words ''Federal Aid

Office'' in both places that they appear and by adding, in each place, the words ''Wildlife and Sport Fish Restoration Office''.

§ 84.48 [Amended]

■ 17. Amend § 84.48, paragraph (a)(5), by removing the words ''Federal Aid program'' and by adding, in their place, the words ''Wildlife and Sport Fish Restoration program''.

§ 84.49 [Amended]

■ 18. Amend § 84.49, by removing the words ''the Washington Office'' in both places they appear and by adding, in each place, the word ''Headquarters''.

PART 85—CLEAN VESSEL ACT GRANT PROGRAM

■ 19. The authority citation for part 85 continues to read as follows:

Authority: 16 U.S.C. 777g(c).

■ 20. Amend § 85.21 by revising paragraph (a) to read as follows:

§ 85.21 Application procedures.

(a) Eligible applicants will submit their proposals to the appropriate regional office of the U.S. Fish and Wildlife Service. Coastal States submitting proposals for both the coastal zone and the inland portion of their States must submit two separate proposals. The regional office addresses are provided at 50 CFR 2.2. Telephone and fax numbers of the regional offices follow:

Region	Wildlife and sport fish restoration telephone number	Wildlife and sport fish restoration fax number
1	503–231–6128	503–231–6996
2	505–248–7465	505–248–7471
3	612–713–5130	612–713–5290
4	404–679–4159	404–679–4160
5	413–253–8508	413–253–8487
6	303–236–4411	303–236–8192
7	907–786–3545	907–786–3575
8	916–414–6509	916–978–6155

* * * * *

§ 85.31 [Amended]

■ 21. Amend § 85.31 by:

■ a. Removing the words ''Division of Federal Aid'' in both places they appear and by adding, in each place, the words ''Wildlife and Sport Fish Restoration programs''; and

■ b. Removing the words ''Washington Office'' and by adding, in their place, the word ''Headquarters''.

§ 85.47 [Amended]

■ 22. Amend § 85.47 by:

■ a. Removing the number ''80.26'' wherever it appears in paragraph (a), (b), (c), and by adding, in each place, the number ''80.99''; and

■ b. Amending paragraph (c) by removing the words ''Federal Aid'' and by adding, in their place, the words ''Wildlife and Sport Fish Restoration''.

PART 100—SUBSISTENCE MANAGEMENT REGULATIONS FOR PUBLIC LANDS IN ALASKA

■ 23. The authority citation for part 100 continues to read as follows:

Authority: 16 U.S.C. 3, 472, 551, 668dd, 3101–3126; 18 U.S.C. 3551–3586; 43 U.S.C. 1733.

■ 24. Amend § 100.22 by revising paragraph (b) to read as follows:

§ 100.22 Subsistence resource regions.

* * * * *

(b) You may obtain maps delineating the boundaries of subsistence resource regions from the U.S. Fish and Wildlife Service at the Alaska Regional Office address provided at 50 CFR 2.2(g).

* * * * *

■ 25. Amend § 100.23 by:

■ a. Removing the second sentence of paragraph (a); and

■ b. Adding paragraph (b) to read as follows:

§ 100.23 Rural determinations.

* * * * *

(b) You may obtain maps delineating the boundaries of nonrural areas from the U.S. Fish and Wildlife Service at the Alaska Regional Office address provided at 50 CFR 2.2(g).

Dated: May 28, 2013.

Rachel Jacobson,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2013–13902 Filed 6–11–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 130108020–3409–01]

RIN 0648–XC705

Fisheries Off West Coast States; Modifications of the West Coast Commercial Salmon Fisheries; Inseason Actions #4 and #5

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Modification of fishing seasons and landing and possession limits; request for comments.

SUMMARY: NOAA Fisheries announces two inseason actions in the ocean salmon fisheries. These inseason actions modified the commercial fisheries in the area from U.S./Canada Border to Queets River.

DATES: The effective dates for the inseason actions are set out in this document under the heading Inseason Actions. Comments will be accepted through June 27, 2013.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2012–0248, by any one of the following methods:

• *Electronic Submissions:* Submit all electronic public comments via the Federal eRulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA–NMFS–2012–0248*, click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* William W. Stelle, Jr., Regional Administrator, Northwest Region, NMFS, 7600 Sand Point Way NE., Seattle, WA, 98115–6349

• *Fax:* 206–526–6736, Attn: Peggy Mundy

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

FOR FURTHER INFORMATION CONTACT: Peggy Mundy at 206–526–4323.

SUPPLEMENTARY INFORMATION:

Background

In the 2013 annual management measures for ocean salmon fisheries (78 FR 25865, May 3, 2013), NMFS announced the commercial and recreational fisheries in the area from the U.S./Canada Border to the U.S./Mexico Border, beginning May 1, 2013, and 2014 salmon seasons opening earlier than May 1, 2014. These management measures include a May–June guideline of 8,700 Chinook salmon

in the area between the U.S./Canada Border and the Queets River, with provisions for an inseason conference call when it is projected that 6,525 Chinook will be landed in this area to consider modifying the open period and adding a landing and possession limit to ensure the 8,700 Chinook guideline is not exceeded (78 FR 25865, May 3, 2013).

NMFS is authorized to implement inseason management actions to modify fishing seasons and quotas as necessary to provide fishing opportunity while meeting management objectives for the affected species (50 CFR 660.409). Inseason actions in the salmon fishery may be taken directly by NMFS (50 CFR 660.409(a)—Fixed inseason management provisions) or upon consultation with the Pacific Fishery Management Council (Council) and the appropriate State Directors (50 CFR 660.409(b)—Flexible inseason management provisions). Prior to taking flexible inseason action, the Regional Administrator (RA) consults with the Chairman of the Pacific Fishery Management Council (Council) and the appropriate State Directors (50 CFR 660.409(b)(1)).

Management of the salmon fisheries is generally divided into two geographic areas: north of Cape Falcon (U.S./Canada Border to Cape Falcon, Oregon) and south of Cape Falcon (Cape Falcon, Oregon to the U.S./Mexico Border). The inseason actions in this document apply north of Cape Falcon.

Inseason Action

Inseason Action #4

The RA consulted with representatives of the Council, Washington Department of Fish and Wildlife (WDFW), and Oregon Department of Fish and Wildlife (ODFW) on May 20, 2013.

The information considered during this consultation related to catch and effort to date in the commercial salmon fishery from the U.S./Canada Border to the Queets River. Inseason action #4 closed the commercial salmon fishery in this area at 11:59 p.m. (midnight), May 20, 2013 due to projected attainment of the 6,525 interim guideline for Chinook salmon catch in the area and to provide a more complete accounting of the catch to date before proceeding with additional fisheries. On May 20, 2013, the states recommended this action and the RA concurred; inseason action #4 took effect on May 20, 2013, and remained in effect until May 24, 2013. Inseason action to modify quotas and/or fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

Inseason Action #5

The RA consulted with representatives of the Council, WDFW, and ODFW on May 23, 2013.

The information considered during this consultation related to catch and effort to date in the commercial salmon fishery from the U.S./Canada Border to the Queets River. Inseason action #5 reopened the commercial salmon fishery in this area at 12:01 a.m. (midnight), May 24, 2013 through 11:59 p.m. (midnight), May 28, 2013 with a landing and possession limit of 28 Chinook salmon per vessel. Vessels that fish during this open period and north of the Queets River are limited to a total landing and possession limit of 28 Chinook regardless of area of catch until the catch from their trip has been delivered. This action was taken to allow access to remaining salmon quota in the area without exceeding the quota. On May 23, 2013, the state of Washington recommended this action and the RA concurred; inseason action #5 took effect on May 24, 2013, and remained in effect through May 28, 2013. Inseason action to modify quotas and/or fishing seasons is authorized by 50 CFR 660.409(b)(1)(i).

All other restrictions and regulations remain in effect as announced for the 2013 Ocean Salmon Fisheries and 2014 fisheries opening prior to May 1, 2014 (78 FR 25865, May 3, 2013).

The RA determined that the best available information indicated that catch and effort projections supported the above inseason actions recommended by the State of Washington. The state manages the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone in accordance with these Federal actions. As provided by the inseason notice procedures of 50 CFR 660.411, actual notice of the described regulatory actions was given, prior to the time the action was effective, by telephone hotline number 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF–FM and 2182 kHz.

Classification

The Assistant Administrator for Fisheries, NOAA (AA), finds that good cause exists for this notification to be issued without affording prior notice and opportunity for public comment under 5 U.S.C. 553(b)(B) because such notification would be impracticable. As previously noted, actual notice of the regulatory actions was provided to fishers through telephone hotline and radio notification. These actions comply with the requirements of the annual management measures for ocean salmon fisheries (78 FR 25865, May 3, 2013), the West Coast Salmon Fishery Management Plan (Salmon FMP), and regulations implementing the Salmon FMP, 50 CFR 660.409 and 660.411. Prior notice and opportunity for public comment was impracticable because NMFS and the state agencies had insufficient time to provide for prior notice and the opportunity for public comment between the time the catch and effort projections were developed and fisheries impacts calculated, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best available scientific information, thus allowing fishers access to the available fish at the time the fish were available while ensuring that quotas are not exceeded. The AA also finds good cause to waive the 30-day delay in effectiveness required under 5 U.S.C. 553(d)(3), as a delay in effectiveness of these actions would allow fishing at levels inconsistent with the goals of the Salmon FMP and the current management measures.

These actions are authorized by 50 CFR 660.409 and 660.411 and are exempt from review under Executive Order 12866.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: June 7, 2013.

Kara Meckley,

Acting Deputy Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2013–13986 Filed 6–11–13; 8:45 am]

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Proposed Rules

Federal Register

Vol. 78, No. 113

Wednesday, June 12, 2013

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 317

[Docket No. FDA–2012–N–1037]

RIN 0910–AG92

Establishing a List of Qualifying Pathogens Under the Food and Drug Administration Safety and Innovation Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA or Agency) is proposing a regulation to establish a list of ''qualifying pathogens'' that have the potential to pose a serious threat to public health. The proposed rule would implement a provision of the Generating Antibiotic Incentives Now (GAIN) title of the Food and Drug Administration Safety and Innovation Act (FDASIA). GAIN is intended to encourage development of new antibacterial and antifungal drugs for the treatment of serious or life-threatening infections, and provides incentives such as eligibility for designation as a fast-track product and an additional 5 years of exclusivity to be added to certain exclusivity periods. FDA is proposing that the following pathogens comprise the list of ''qualifying pathogens:'' *Acinetobacter* species, *Aspergillus* species, *Burkholderia cepacia* complex, *Campylobacter* species, *Candida* species, *Clostridium difficile, Enterobacteriaceae* (e.g., *Klebsiella pneumoniae*), *Enterococcus* species, *Mycobacterium tuberculosis* complex, *Neisseria gonorrhoeae, N. meningitidis,* Non-tuberculous mycobacteria species, *Pseudomonas* species, *Staphylococcus aureus, Streptococcus agalactiae, S. pneumoniae, S. pyogenes,* and *Vibrio cholerae.* The preamble to the proposed rule describes the factors we considered and the methodology we used to develop this list of qualifying pathogens.

DATES: Submit comments by August 12, 2013.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–1037 and/or Regulatory Information Number (RIN) 0910–AG92, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name, Docket No. FDA–2012–N–1037 and RIN 0910–AG92 for this rulemaking. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Kristiana Brugger, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 51, Rm. 6262, Silver Spring, MD 20993–0002, 301–796–3601.

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I. Executive Summary

Purpose of the Regulatory Action

Title VIII of FDASIA (Pub. L. 112–144), the GAIN title, is intended to encourage development of new antibacterial and antifungal drugs for the treatment of serious or life-threatening infections. Among other things, it requires that the Secretary of the Department of Health and Human Services (and thus FDA, by delegation): (1) Establish and maintain a list of ''qualifying pathogens'' that have ''the potential to pose a serious threat to public health'' and (2) make public the methodology for developing the list (see section 505E(f) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended) (21 U.S.C. 355E(f)). In establishing and maintaining the list of ''qualifying pathogens,'' FDA must consider: The impact on the public health due to drug-resistant organisms in humans; the rate of growth of drug-resistant organisms in humans; the increase in resistance rates in humans;

and the morbidity and mortality in humans. FDA also is required to consult with infectious disease and antibiotic resistance experts, including those in the medical and clinical research communities, along with the Centers for Disease Control and Prevention (CDC). FDA is issuing this proposed rule to fulfill these requirements.

Summary of the Major Provisions of the Regulatory Action

After holding a public meeting and consulting with CDC and the National Institutes of Health (NIH), and considering the factors specified in section 505E(f)(2)(B)(i) of the FD&C Act, as amended, FDA is proposing that the following pathogens comprise the list of ''qualifying pathogens:'' *Acinetobacter* species, *Aspergillus* species, *Burkholderia cepacia* complex, *Campylobacter* species, *Candida* species, *Clostridium difficile, Enterobacteriaceae* (e.g., *Klebsiella pneumoniae*), *Enterococcus* species, *Mycobacterium tuberculosis* complex, *Neisseria gonorrhoeae, N. meningitidis,* Non-tuberculous mycobacteria species, *Pseudomonas* species, *Staphylococcus aureus, Streptococcus agalactiae, S. pneumoniae, S. pyogenes,* and *Vibrio cholerae.* The preamble to the proposed rule describes the factors FDA considered and the methodology FDA used to develop this list of qualifying pathogens.

Costs and Benefits

The Agency has determined that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

II. Background

Title VIII of FDASIA (Pub. L. 112–144), entitled Generating Antibiotic Incentives Now, amended the FD&C Act to add section 505E (21 U.S.C. 355E), among other things. This new section of the FD&C Act is intended to encourage development of treatments for serious or life-threatening infections caused by bacteria or fungi. For certain drugs that are designated as ''qualified infectious disease products'' (QIDPs) under new section 505E(d) of the FD&C Act, new section 505E(a) provides an additional 5 years of exclusivity to be added to the exclusivity periods provided by sections 505(c)(3)(E)(ii) to (c)(3)(E)(iv) (21 U.S.C. 355(c)(3)(E)(ii) to (c)(3)(E)(iv)), 505(j)(5)(F)(ii) to (j)(5)(F)(iv) (21 U.S.C. 355(j)(5)(F)(ii) to (j)(5)(F)(iv)), and 527 (21 U.S.C. 360cc) of the FD&C Act. In addition, an application for a drug designated as a QIDP is eligible for priority review and designation as a fast track product (sections 524A and 506(a)(1) of the FD&C Act, respectively).

The term ''qualified infectious disease product'' or ''QIDP'' refers to an antibacterial or antifungal human drug that is intended to treat serious or life-threatening infections (section 505E(g) of the FD&C Act). It includes treatments for diseases caused by antibacterial- or antifungal-resistant pathogens (including new or emerging pathogens), or diseases caused by ''qualifying pathogens.''

The GAIN title of FDASIA requires that the Secretary of the Department of Health and Human Services (and thus FDA, by designation) establish and maintain a list of such ''qualifying pathogens,'' and make public the methodology for the developing the list. According to the statute, the term 'qualifying pathogen' means a pathogen identified and listed by the Secretary * * * that has the potential to pose a serious threat to public health, such as[:] (A) resistant gram positive pathogens, including methicillin-resistant *Staphylococcus aureus,* vancomycin-resistant *Staphylococcus aureus,* and vancomycin-resistant *[E]nterococcus;* (B) multi-drug resistant gram[-]negative bacteria, including *Acinetobacter, Klebsiella, Pseudomonas,* and *E. coli* species; (C) multi-drug resistant tuberculosis; and (D) *Clostridium difficile* (section 505E(f)(1) of the FD&C Act, as amended by FDASIA). FDA is required under the law to consider four factors in establishing and maintaining the list of qualifying pathogens:

- The impact on the public health due to drug-resistant organisms in humans;
- The rate of growth of drug-resistant organisms in humans;
- The increase in resistance rates in humans; and
- The morbidity and mortality in humans (section 505E(f)(2)(B)(i), as amended by FDASIA).

Furthermore, in determining which pathogens should be listed, FDA is required to consult with infectious disease and antibiotic resistance experts, including those in the medical and clinical research communities, along with CDC (section 505E(f)(2)(B)(ii) of the FD&C Act, as amended by FDASIA). As discussed in the paragraphs that follow, FDA has met this requirement by convening a public hearing, and opening an associated public docket, to solicit input regarding the list of qualifying pathogens, as well as by consulting with infectious disease and antibiotic resistance experts at CDC and NIH during the development of this proposed rule.

Significantly, the statutory standard for inclusion on FDA's list of qualifying pathogens is different from the statutory standard for QIDP designation. QIDP designation, by definition, requires that the drug in question be an ''antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections'' (section 505E(g) of the FD&C Act, as amended by FDASIA). ''Qualifying pathogens'' are defined according to a different statutory standard; the term ''means a pathogen identified and listed by the Secretary . . . that has the *potential* to pose a serious threat to public health'' (section 505E(f) of the FD&C Act, as amended by FDASIA) (emphasis added). That is, a drug intended to treat a serious or life-threatening bacterial or fungal infection caused by a pathogen that is not included on the list of ''qualifying pathogens'' may be eligible for designation as a QIDP, while a drug that is intended to treat an infection caused by a pathogen on the list may not always be eligible for QIDP designation.

FDA intends the list of qualifying pathogens to reflect the pathogens that, as determined by the Agency, after consulting with other experts and considering the factors set forth in FDASIA (see section 505E(f)(2)(B)(i) of the FD&C Act, as amended by FDASIA), have the ''potential to pose a serious threat to public health'' (section 505E(f)(1) of the FD&C Act, as amended by FDASIA). FDA does not intend for this list to be used for other purposes, such as the following: (1) Allocation of research funding for bacterial or fungal pathogens; (2) setting of priorities in research in a particular area pertaining to bacterial or fungal pathogens; or (3) direction of epidemiological resources to a particular area of research on bacterial or fungal pathogens. Furthermore, as section 505E of the FD&C Act makes clear, the list of qualifying pathogens includes only bacteria or fungi that have the potential to pose a serious threat to public health. Viral pathogens or parasites, therefore, were not considered for inclusion and are not included as part of this list.

III. Consultation With Infectious Disease and Antibiotic Resistance Experts

GAIN requires FDA to consult with infectious disease and antibiotic resistance experts, including those in the medical and clinical research communities, along with the CDC, in determining which pathogens should be included on the list of ''qualifying pathogens'' (section 505E(f)(2)(B)(ii) of the FD&C Act, as amended by FDASIA).

In order to fulfill this statutory obligation, on December 18, 2012, FDA convened a public hearing, at which the Agency solicited input regarding the following topics: (1) How FDA should interpret and apply the four factors FDASIA requires FDA to ''consider'' in establishing and maintaining the list of qualifying pathogens, (2) whether there are any other factors FDA should consider when establishing and maintaining the list of qualifying pathogens, and (3) which specific pathogens FDA should list as qualifying pathogens. The transcript of this hearing, as well as comments submitted to the hearing docket, are available at *www.regulations.gov,* docket number FDA–2012–N–1037. FDA has considered carefully the input presented at this hearing, as well as the comments submitted to the docket, in creating this proposed list of qualifying pathogens.[1] In addition, FDA consulted with experts in infectious disease and antibiotic resistance at CDC and NIH during the development of this proposed rule.

IV. Factors Considered and Methodology Used for Establishing a List of Qualifying Pathogens

As stated previously, section 505E(f)(2)(B)(i) of the FD&C Act (as amended by FDASIA) requires FDA to consider the following factors in establishing and maintaining the list of qualifying pathogens:

- The impact on the public health due to drug-resistant organisms in humans;
- The rate of growth of drug-resistant organisms in humans;
- The increase in resistance rates in humans; and
- The morbidity and mortality in humans.

The Agency recognizes it is important to take a long-term view of the drug resistance problem. For some pathogens, particularly those for which increased resistance is newly emerging, FDA recognizes that there may be gaps in the available data or evidence pertaining to one or more of the four factors described in section 505E(f)(2)(B)(i) of the FD&C Act. Thus, consistent with GAIN's purpose of encouraging the development of treatments for serious or life-threatening infections caused by bacteria or fungi, the Agency intends to consider the totality of available evidence for a particular pathogen to determine whether that pathogen should be included on the list of qualifying pathogens. Therefore, if, after considering the four factors identified in section 505E(f)(2)(B)(i) of the FD&C Act, FDA determines that the totality of available evidence demonstrates that a pathogen ''has the potential to pose a serious threat to public health,'' the Agency may designate the pathogen in question as a ''qualifying pathogen.'' More detailed explanations of each factor identified in section 505E(f)(2)(B)(i) are set forth in the paragraphs that follow.

A. The Impact on the Public Health Due to Drug-Resistant Organisms in Humans

This first factor that section 505E(f)(2)(B)(i) requires FDA to consider is also the broadest. Many factors associated with infectious diseases affect public health directly, such as a pathogen's ease of transmission, the length and severity of the illness it causes, the risk of mortality associated with its infection, and the number of approved products available to treat illnesses it causes. Additionally, although the Agency did not consider financial costs in its analyses for this proposed list of qualifying pathogens, we note that the published literature supports the conclusion that antimicrobial-resistant infections are associated with higher healthcare costs (see, e.g., Refs. 1 and 2; Ref. 3 at pp. 807, 810, 812).

In considering a proposed pathogen's impact on the public health due to drug-resistant organisms in humans, FDA will assess such evidence as: (1) The transmissibility of the pathogen and (2) the availability of effective therapies for treatment of infections caused by the pathogen, including the feasibility of treatment administration and associated adverse effects. However, FDA may also assess other public health-related evidence, including evidence that may indicate a highly prevalent pathogen's ''potential to pose a serious threat to public health'' due to the development of drug-resistance in that pathogen, even if most documented infections are currently drug-susceptible.

B. The Rate of Growth of Drug-Resistant Organisms in Humans and the Increase in Resistance Rates in Humans

The second and third factors that FDA must consider overlap substantially with one another, and for the most part are assessed using the same trends and information. Therefore, the Agency will analyze these factors together.

In considering these factors with respect to a proposed pathogen, FDA will assess such evidence as: (1) The proportion of patients whose illness is caused by a drug-resistant isolate of a pathogen (compared with those whose illness is caused by more widely drug-susceptible pathogens); (2) number of resistant clinical isolates of a particular pathogen (e.g., the known incidence or prevalence of infection with a particular resistant pathogen); and (3) the ease and frequency with which a proposed pathogen can transfer and receive resistance-conferring elements (e.g., plasmids encoding relevant enzymes, etc.). Given the temporal limitations on infectious disease data, FDA also will consider evidence that a given pathogen currently has a strong potential for a meaningful increase in resistance rates. Evidence of the potential for increased resistance may include, for example, projected (rather than observed) rates of drug resistance for a given pathogen, and current and projected geographic distribution of a drug-resistant pathogen. Furthermore, in acknowledgement of the growing problem of drug resistance, FDA may also assess other available evidence demonstrating either existing or potential increases in drug resistance rates.

C. The Morbidity and Mortality in Humans

Patients infected with drug-resistant pathogens are inherently more challenging to treat than those infected with drug-susceptible pathogens. For example, in some cases, a patient infected with a drug-resistant pathogen may have a delay in the initiation of effective drug therapy that can result in poor outcomes for such patients. Consequently, in determining whether a pathogen should be included in the list, FDA will consider the rates of mortality and morbidity (the latter as measured by, e.g., duration of illness, severity of illness, and risk and extent of sequelae from infections caused by the pathogen, and risk associated with existing treatments for such infections) associated with infection by that pathogen generally—and particularly by drug-resistant strains of that pathogen.

Setting quantitative thresholds for inclusion on the list based on any pre-specified endpoint would be inconsistent with FDA's approach of considering a totality of the evidence related to a given pathogen, as well as infeasible given the variety of pathogens under consideration. Instead, in considering whether this factor weighs in favor of including a given pathogen, the Agency will look for evidence of a meaningful increase in morbidity and mortality rates when infection with a drug-resistant strain of a pathogen is compared to infection with a more drug-

[1] The public hearing and this proposed rule share docket numbers because they are part of the same rulemaking process. Accordingly, the documents from the public hearing phase of Docket No. FDA–2012–N–1037 are included in the docket for this rulemaking.

susceptible strain of that pathogen. The Agency may also assess other evidence, such as overall morbidity and mortality rates for infection with either resistant or susceptible strains of a pathogen to determine whether that pathogen has the potential to pose a serious threat to public health, in particular if drug-resistant isolates of the pathogen were to become more prevalent in the future.

V. Proposed Pathogens for Inclusion in the List

FDA is proposing to include the following pathogens in its list of qualifying pathogens based on the data described in the paragraphs that follow. FDA expects that the inclusion of any additional pathogens in the list would be supported by similar data.

A. Acinetobacter Species

Members of the genus *Acinetobacter* are gram-negative bacteria that can cause hospital-acquired infections such as pneumonia, bacteremia (i.e., bloodstream infections), meningitis, genitourinary infections, or soft tissue infections (e.g., cellulitis) (Ref. 4 at pp. 2881–2883 (internal citation omitted)). A total of 1,490 healthcare-associated infections with *Acinetobacter* species, the majority of which were resistant to at least one class of antibacterial drugs, were reported to CDC's National Healthcare Safety Network (NHSN) in 2009–2010 (Ref. 132, Table 7). Thus, *Acinetobacter* resistance is a well-recognized and growing problem (see generally, e.g., Ref. 5), and most hospital-acquired *A. baumannii* are now resistant to multiple classes of antibacterial agents (Ref. 4 at p. 2884 (internal citation omitted)). Indeed, in recognition of this problem, in 2008, the Infectious Diseases Society of America (IDSA) designated *Acinetobacter* species to be among six highly problematic drug-resistant organisms identified as the so-called ''ESKAPE'' pathogens, which ''currently cause the majority of U.S. hospital infections and effectively 'escape' the effects of antibacterial drugs.'' [2] (Refs. 5 and 6). *Acinetobacter* species can survive for prolonged periods in the environment and on the hands of healthcare workers, and as such are well-recognized as transmissible nosocomial pathogens (see, e.g., Ref. 7). Several independent resistance mechanisms, such as those mediated by cephalosporinases, beta-lactamases, or carbapenemases, have been identified in *Acinetobacter* species, and some resistance mechanisms (e.g., genes encoding resistance-mediating enzymes) can be readily transferred from one bacteria to another on highly ambulatory genetic cassettes (Ref. 9). In addition, the pool of available effective treatments for *Acinetobacter* infections is shrinking (see, e.g., Ref. 5 at p. 7; Ref. 6).

Patients who acquire a drug-resistant *Acinetobacter* bloodstream infection appear more likely than those with drug-susceptible infections to suffer deleterious effects from the illness. For example, in a study of patients with *A. baumannii* bloodstream infections in European intensive care units (ICUs), 74 percent of *A. baumannii* bloodstream infections were resistant to a commonly used antibacterial drug (Ref. 10 at p. 33, Table 3).[3] Patients with resistant *A. baumannii* bloodstream infections became infected sooner after admission than patients with drug-susceptible *A. baumannii* (9 days vs. 19 days) (Ref. 10 at p. 33, Table 3). For those who survived, patients infected with resistant bacteria remained in the hospital longer than those infected with susceptible bacteria (20 days vs. 9 days), and, for those who died,[4] patients infected with resistant bacteria died sooner after infection than those with susceptible bacteria (5 days vs. 16 days) (Ref. 10 at p. 33, Table 3). In addition, ''recent studies of patients in the [ICU] who had [bloodstream infection] and burn infection due to [drug]-resistant *Acinetobacter* species demonstrate an increased mortality (crude mortality, 26 to 68 percent), as well as increased morbidity and length of stay in the [ICU]'' (Ref. 5 at p. 7). Similar trends have been seen for *A. baumannii* pneumonia in terms of: Prevalence of drug-resistant infection; time from admission to infection; and time from infection to death (Ref. 10).[5] In one study of Pakistani newborns with infections caused by *Acinetobacter* species, 57 of 122 *Acinetobacter*-positive cultures (from 78 newborns) showed infection in the bloodstream (Ref. 133). Approximately 71 percent of all *Acinetobacter* infections in the study were susceptible to only one antibacterial drug (polymyxin), and were labeled as a ''pan-resistant'' (i.e., resistant to many drugs) *Acinetobacter;* 47 percent of the newborns in the study with *Acinetobacter* infections died (Ref. 133).

For the reasons described previously, FDA believes that *Acinetobacter* species have the potential to pose a serious threat to the public health, particularly for hospitalized patients and, FDA is proposing to include *Acinetobacter* species in its list of qualifying pathogens.

B. Aspergillus Species

Members of the *Aspergillus* genus are fungi (specifically, hyaline molds) that have potential to cause serious infections, typically in immunocompromised people. *Aspergillus* can cause invasive infections of the lungs, skin, sinuses, bone, or brain, or be disseminated throughout the body. It frequently colonizes airway passages, creating the potential for invasive disease among patients who become immunocompromised, such as patients who receive lung transplantation (Ref. 11). In one center, for example, *Aspergillus* infection (i.e., colonization or evidence of invasive disease) was reported in approximately 30 percent of patients who received lung transplantation (Ref. 11). These fungi also may cause an allergic reaction, which may result in allergic bronchopulmonary aspergillosis, particularly in those with cystic fibrosis (CF) (Ref. 4 at pp. 3241, 3244–3249).

Invasive aspergillosis often responds poorly to antifungal therapy, even when *Aspergillus* infections are susceptible to antifungal drugs (Ref. 4 at p. 3250). Therefore, the existence throughout the world of azole-resistant *A. fumigatus* (i.e., *A. fumigatus* isolates resistant to the class of drugs comprising several different antifungal drugs in the family of ''azole antifungal drugs''), and reports that azole resistant *A. fumigatus* may be spreading in the environment (see Ref. 12 at pp. 1635–1636) is of great concern—as are the reports of multiple-drug resistant *A. fumigatus* in Europe

[2] The ''ESKAPE'' pathogens are: *Enterococcus faecium, S. aureus, Klebsiella pneumoniae, A. baumanni, Pseudomonas aeruginosa,* and *Enterobacter* species (Ref. 6).

[3] All figures represent data for those strains of *A. baumannii* whose resistance status was known, which was approximately 29 percent of all patients with *A. baumannii* bloodstream infections (Ref. 10). Numbers indicate median values (id.).

[4] The point estimate of the case fatality rate for *A. baumannii* bloodstream infections among patients in which the results of in vitro antibacterial susceptibility testing were not available for most isolates, was very high at 48 percent (68/142). The point estimate of the case fatality rate was slightly lower for known resistant infections (13/30 or 43 percent), compared to known susceptible infections (6/11 or 55 percent) (Ref. 10 at pp. 33–34). The small denominator of patients with known susceptible *A. baumannii* bloodstream infections makes it difficult to draw conclusions about a difference in mortality rates based on the in vitro susceptibility profiles; therefore any *A. baumannii* bloodstream infection, the majority of which appear to be resistant to many antibacterial drugs, is associated with a high mortality rate.

[5] For *A. baumannii* pneumonia, results of in vitro susceptibility was known for only 34 percent of patients (Ref. 10).

(Refs. 12 and 13). The predominant resistance mechanism in *A. fumigatus* is thought to be a chromosomally encoded mutation in the target enzyme, although alternative resistance mechanisms have been observed (see, e.g., Ref. 13). In some cases antifungal drugs are recommended as chemical prophylaxis to prevent invasive infections in high-risk patients (Ref. 4 at p. 3253), including some asthmatics (see Ref. 13). However, the use of prophylactic antifungal drugs creates selective pressure on these organisms, thus increasing the risk of drug-resistant *Aspergillus* colonization and infection. Moreover, European studies have found that many patients who had not received antifungal therapy nevertheless were colonized with resistant strains of *A. fumigatus* (Ref. 13 (internal citations omitted)).

Many patients with *Aspergillus* infections are vulnerable already, due to concomitant conditions such as cystic fibrosis or some level of immunodeficiency. Should *Aspergillus* resistance further diminish the already low efficacy of existing treatments and prophylaxis, patient outcomes would, similarly, be expected to worsen. For the reasons described above, FDA believes that *Aspergillus* species have the potential to pose a serious threat to the public health, and FDA is proposing to include *Aspergillus* species in its list of qualifying pathogens.

C. Burkholderia cepacia Complex

The *Burkholderia cepacia* complex (Bcc) comprises about 10 species of gram-negative bacteria (Ref. 4 at p. 2861). The *Burkholderia* genus was established relatively recently, however, and species are being identified and added to the Bcc on an ongoing basis (Ref. 4 at p. 2861). Bcc can cause pneumonia, particularly in patients with CF and patients with chronic granulomatous disease (Ref. 4 at pp. 2862, 2865 (internal citation omitted)). Bcc can also cause life-threatening bacteremia among hospitalized patients who are immunocompromised, resulting in a mortality rate of 33 percent of hematology patients with Bcc bacteremia in one academic medical center (Ref. 14). Other outbreaks of serious bacterial infections caused by Bcc have been documented due to nosocomial transmission, indicating the potential for an ease of transmissibility in the hospital setting in patients without CF (see, e.g., Ref. 15).

Bcc infections cause noteworthy levels of morbidity and mortality, particularly in patients with CF (see, e.g., Ref. 14), although outbreaks among patients without CF also have been reported (see, e.g., Ref. 16). ''Increased mortality has been observed in CF patients after colonization with Bcc,'' (Ref. 4 at p. 2865 (internal citations omitted); Ref. 17) and, in one study, survival rates for patients with CF who were infected with *B. cenocepacia* (a Bcc species) were markedly worse than rates for patients with CF who were infected with *P. aeruginosa* (not a Bcc species) (Ref. 150; see also Ref. 4 at p. 2862, Fig. 220–1 (internal citation omitted)). Because patients with CF often require repeated or chronic administration of antibacterial drugs, antibacterial drug resistance among Bcc isolates can develop through these selective pressures (see Ref. 18 (noting that an increase in antibacterial resistance was observed among patients with CF who received a chronically inhaled antibacterial drug)). In fact, a pan-resistant isolate of Bcc already has been documented in patients with CF (Ref. 19). Although there appear to be limited data on the exact incidence and prevalence of Bcc infection in the CF population, because the average life-span for patients with CF has been steadily increasing over the past few decades (Ref. 20 at p. 789, Fig. 1), it stands to reason that Bcc colonization and infection in patients with CF likely will increase. Furthermore, although data comparing outcomes of drug-resistant infections with outcomes of drug-susceptible infections also are limited, it stands to reason that decreasing susceptibility and resistance patterns in Bcc likely will be observed during the life span of a patient with CF based on selective pressures caused by appropriate use of antibacterial drugs.

For the reasons described previously, FDA believes that these pathogens have the potential to pose a serious threat to the public health—particularly for patients with CF—and FDA is proposing to include Bcc species in its list of qualifying pathogens.

D. Campylobacter Species

The *Campylobacter* genus comprises several species of gram-negative bacteria, some of which are causative agents of diarrheal and systemic diseases in humans (Ref. 4 at pp. 2793–2796). These are common infections: *Campylobacter* is estimated to cause over 1.3 million cases of enteric infection in the United States each year (Ref. 42). It is believed that most human infections are caused by consuming contaminated food (e.g., meat) or water (Ref. 4 at p. 2794), though person to person transmission of *C. jejuni* has been reported to occur through the fecal-oral route, and other routes (Ref. 4 at p. 2795). Transmissibility is readily apparent, with clinical disease that can be caused by just 500 *Campylobacter* organisms (Ref. 4 at p. 2795), so, for example, ''[e]ven one drop of juice from raw chicken meat can infect a person'' (Ref. 21).

The following indicates the potential for *Campylobacter* infections to result in enhanced morbidity and mortality, regardless of whether the bacterium is fully susceptible or is resistant to antibacterial drugs: *C. jejuni* infections have been linked to reactive arthritis in a certain subset of patients (Ref. 4 at p. 2797), *C. jejuni* infections are a major cause of Guillain-Barré syndrome (1 case per 2,000 *C. jejuni* infections, accounting for 20 to50 percent of all cases of Guillain-Barré syndrome (*id.*)), and *C. fetus* infections ''may be lethal to patients with chronic compensated diseases such as cirrhosis or diabetes mellitus or may hasten the demise of seriously compromised patients'' (Ref. 4 at p. 2799). Although many people recover from enteric *Campylobacter* infections without the need for drug treatment, a variety of antibacterial drugs, including azithromycin, erythromycin, or ciprofloxacin, may be prescribed to treat severe *Campylobacter* infections (Ref. 21; Ref. 4 at p. 2799).

Drug resistance in *Campylobacter* species, particularly resistance to fluoroquinolones, has been increasing rapidly (Ref. 4 at p. 2799 (internal citation omitted); see Ref. 22; see also Ref. 134). Indeed, in human *Campylobacter* infections, resistance has been observed to many different classes of antibacterial drugs (see, e.g., Ref. 22 (internal citations omitted); Ref. 23), and resistance mechanisms can be readily transferred from bacteria to bacteria (Ref. 22). ''Infection with *C. jejuni* strains resistant to erythromycin or fluoroquinolones is more likely to result in prolonged or invasive illness or death'' (Ref. 4 at p. 2799), and it stands to reason that drug-resistant strains of other pathogenic *Campylobacter* species are likely to be similarly problematic. One survey of *Campylobacter* isolates indicated increasing and high levels of resistance to antibacterial drugs in several classes, with some of the resistance encoded on transferable plasmids (Ref. 24). Because *Campylobacter* infections are common, any increase in resistance rates may translate quickly into a threat to the public health.

For the foregoing reasons, FDA believes that *Campylobacter* species have the potential to pose a serious threat to public health, and FDA is proposing to include bacteria from the

genus *Campylobacter* in the list of qualifying pathogens.

E. Candida Species

Candida species are fungi (specifically, yeast) that are part of the normal human flora, and thus *Candida* species can easily be transmitted and can cause invasive disease, particularly among immunocompromised patients (see, e.g., Ref. 4 at pp. 3225–3226; Ref. 25). *Candida* can infect almost any part of the body to which they are introduced (so-called invasive candidiasis), including the central nervous system, respiratory tract, urinary tract, gastro-intestinal tract, or heart (see Ref. 4 at pp. 3227–3235).

Those who are already fragile are at higher risk of invasive disease (e.g., between 5 percent and 20 percent of neonates weighing less than 2.2 pounds will develop some form of invasive candidiasis (Ref. 26)), and the risk is particularly high in those who are immunocompromised. For example, before the availability of highly-active antiretroviral therapy for the treatment of human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), invasive candidiasis (such as esophageal candidiasis) was a common infection in this patient population, with a well-documented increase in the rates of antifungal resistance (Ref. 27). Many patients with HIV/AIDS did not respond to standard antifungal therapy and required administration of parenteral antifungal drugs, which limited therapeutic options and was directly associated with the development of resistance (Ref. 27). Today, infections caused by *Candida* species rank as the fourth most common bloodstream infection in the United States (Ref. 25). *Candida* bloodstream infections are associated with high mortality rates, with approximately 35 to 40 percent of infected patients dying of *Candida* infections in a study involving patients in one tertiary-care center (Ref. 28).

Although the problem of invasive candidiasis has diminished in the population of patients with HIV/AIDS due to advances in antiretroviral therapy, the number of patients receiving solid organ transplants, and therefore on immunosuppressive therapy, is increasing (Ref. 29). Experts are now concerned about antifungal-resistant invasive candidiasis in this patient population, echoing the concerns previously borne out in the population of patients with HIV/AIDS (see, e.g., Refs. 27 and 30). Transplant patients often take prophylactic antifungal drugs, which exert selective pressure on the *Candida* organisms and make it more likely that these patients will be colonized by, or develop infections with, drug-resistant fungi. Indeed, it has been noted that *Candida* species with antifungal resistance patterns are emerging as a common fungal infection in this population (Refs. 28 and 30).

Resistance genes in *Candida* species tend to proliferate in localized populations, though they occasionally may be transferred through mating (Ref. 31). Some reports have documented continued selective pressures of oral antifungal drugs administered as prophylaxis in certain populations, resulting in an increasing rate of infection caused by *Candida* species resistant to ''azole antifungal drugs'' (e.g., *Candida glabrata* and *Candida krusei*) (see, e.g., Refs. 32 and 33). Selective pressures from the use of oral azole antifungal drugs can shift infections from *C. albicans* to certain other *Candida* species, such as *Candida glabrata* and *Candida krusei,* which both have intrinsic resistance to azole antifungal drugs and eliminates any possibility of treatment with an oral azole antifungal drug. Thus, some patients with invasive candidiasis already have treatment options limited to only intravenously-administered antifungal drugs (Ref. 34).

For the foregoing reasons, FDA believes that *Candida* species have the potential to pose a serious threat to the public health, and FDA proposes that *Candida* species be included in the list of qualifying pathogens.

F. Clostridium difficile

C. difficile is a toxin-producing gram-positive bacterium (Ref. 35) that can cause serious, sometimes fatal, gastrointestinal disease (e.g., toxic megacolon) (see, e.g., Ref. 4 at p. 3104 (internal citation omitted)). The spores of the *C. difficile* bacteria (see Ref. 36) are difficult to eliminate from the environment, even after disinfection by hand-washing or cleansing, and individuals can acquire the pathogen via contact with either contaminated surfaces or other individuals (see, e.g., Ref. 4 at p. 3104 (internal citation omitted)). CDC estimates that the vast majority of patients with *C. difficile* infection have had recent contact with healthcare providers, either in an inpatient or outpatient setting (Ref. 37). Because spores of the bacteria are difficult to eliminate from the environment, it is not surprising that transmission of *C. difficile* infection in the hospital environment has been noted (Ref. 37).

Risk of infection with *C. difficile* increases with both a patient's age and recent antibacterial drug use (Ref. 37). Incidence of *C. difficile*-associated illness has increased significantly over the past several years. For example, ''[t]here was an 117% increase in the listing of [*C. difficile*-associated disease] on hospital discharges in the Healthcare Costs and Utilization Project Net Web site from 2000 to 2005'' (Ref. 4 at p. 3106 (internal citation omitted)), and currently, ''*C. difficile* infections are at an all-time high'' (Ref. 37). Mortality has been increasing along with infection incidence. One study showed that from 1999 to 2004 in the United States (Ref. 63) there was a 35 percent increase in mortality for which *C. difficile* infection was listed as a contributing factor. CDC has estimated a 400 percent increase in deaths between 2000 and 2007 in which *C. difficile* was a contributing factor (Ref. 37). Currently, based on a review of death certificates, about 14,000 American deaths each year list *C. difficile* infection as a contributing factor; the majority of deaths occur in patients over 65 years of age (Ref. 135).

The use of antibacterial drugs in hospitals has been identified as an important risk factor for *C. difficile* infections because *C. difficile* is naturally resistant to many commonly used antibacterial drugs. However, the prevalence of *C. difficile* infections is increasing and that has been associated with an increased prevalence of strains with new resistance to fluoroquinolones (see, e.g., Ref. 38). North American epidemiological data have shown the emergence of high levels of resistance to fluoroquinolone antibacterial drugs—and this resistance emerged quickly (see, e.g., Ref. 39). As noted by CDC, ''even a modest decrease in [drug] susceptibility might be clinically relevant'' to the epidemiology of *C. difficile* infections (Ref. 38 at p. 446). Newly acquired resistance by *C. difficile* to commonly used antibacterials, as in the case of the fluoroquinolones, facilitates the emergence of hyper-virulent strains that increase the burden of infections and deaths caused by *C. difficile* (Refs. 39 and 156).

C. difficile causes serious infections but there are a limited number of effective antibacterial drugs used to treat *C. difficile* infection, and treatment often lasts for an extended period of time (Ref. 38). Furthermore, relapse or recurrence of *C. difficile* is common, and often necessitates re-treatment with antibacterial drugs (Ref. 38). In light of these considerations, the increased prevalence of *C. difficile* infections constitutes a serious threat to the public health (Ref. 39).

Thus, FDA believes that *C. difficile* has the potential to pose a serious threat

to public health. For the reasons described previously—particularly the high prevalence of *C. difficile* infections, the fact that acquired resistance leads to increased infections and deaths via the emergence of hypervirulent strains, and the very limited treatment options—FDA is proposing to include *C. difficile* in its list of qualifying pathogens.

G. Enterobacteriaceae

The *Enterobacteriaceae* are a family of gram-negative bacteria and include species in the genera *Escherichia* (e.g., *E. coli*), *Klebsiella, Enterobacter, Shigella,* and *Salmonella* (see Ref. 4 at pp. 2815–2816). Most *Enterobacteriaceae* are toxin-secreting, and they can cause a variety of serious and life-threatening bacterial diseases (see Ref. 4 at pp. 2819–2829). For example, bloodstream infections, urinary tract infections, pneumonia, and complicated intra-abdominal infections are commonly caused by *Enterobacteriaceae,* and increasingly these infections are resistant to antibacterial drugs (see, e.g., Refs. 40 and 41). In the United States, there were 1.2 million cases of *Salmonella* infection each year (Ref. 42). In addition, the rate of hospitalization due to bloodstream infections—many of which are caused by *Enterobacteriaceae*—doubled from the years 2000 to 2008 (Ref. 43).

Antimicrobial resistance is already a problem for many genera in this family. For example, enteropathic *E. coli* strains ''are often resistant to multiple antibiotics'' (Ref. 4 at p. 2824 (internal citation omitted)) and ''resistant mutants are already present in most patients with *Enterobacter* infections before initiation of therapy'' (Ref. 4 at p. 2827). Increased resistance in *Shigella* strains has been documented in the United States (Refs. 45 and 154) and abroad (Ref. 44), as has increased resistance in *Salmonella* (Refs. 42 and 155). ''In addition, nosocomial isolates [of *Klebsiella pneumoniae*] are frequently resistant to numerous 'antibacterial drugs' as a result of the acquisition of multidrug-resistant plasmids. For example, *K. pneumoniae* is one of the most common organisms to carry plasmids encoding extended-spectrum [beta]-lactamases, and bacteremia with such strains is associated with higher rates of treatment failure and death'' (Ref. 4 at p. 2826 (internal citation omitted)).

Enterobacteriaceae resistance to beta-lactam drugs, including, for example, cephalosporins, is well-recognized (see generally, e.g., Refs. 46 and 47), and several resistant strains exist (see, e.g., Ref. 47). Extended-spectrum beta-lactamase (EBSL) enzymes may be found in several *Enterobacteriaceae* members, and these enzymes ''confer resistance against all [beta]-lactam antibiotics except carbapenems and cephamycins'' (Ref. 47 at p. 682 (internal citation omitted)).

Additionally, *Enterobacteriaceae* members can become—and, particularly in the case of *K. pneumoniae* and *E. coli,* commonly have become—resistant to carbapenems (carbapenem-resistant *Enterobacteriaceae* or CRE) (see, e.g., Ref. 48), which are beta-lactam antibiotics that ''often are the last line of defense against [g]ram-negative infections that are resistant to other antibiotics'' (Ref. 49). Recently, New Delhi metallo-beta-lactamase (NDM), a plasmid-encoded enzyme that permits bacterial resistance to broad-spectrum beta-lactam drugs, including carbapenems, has been reported in cases of *Enterobacteriaceae* infection in the United States (Refs. 50 and 51). ''CRE containing New Delhi metallo-beta-lactamase (NDM), first reported in a patient who had been hospitalized in New Delhi, India, in 2007, are of particular concern because these enzymes usually are encoded on plasmids that harbor multiple resistance determinants and are transmitted easily to other *Enterobacteriaceae* and other genera of bacteria'' (Ref. 50 (internal citations omitted); see also, e.g., Ref. 4 at p. 2820). A total of 6,470 healthcare-associated infections with *Klebsiella* species were reported to CDC's NHSN in 2009–2010; on average, approximately 11 percent were resistant to carbapenems and approximately 24 percent were non-susceptible to extended-spectrum cephalosporins. Among 9,351 *E. coli* infections reported to NHSN in 2009–2010, approximately 2 percent were resistant to carbapenems and approximately 12 percent were non-susceptible to extended-spectrum cephalosporins (Ref. 132, table 7).

Although NDM-related resistance is only one example, drug-resistance genes in *Enterobacteriaceae* ''may be present on transposons, allowing them to jump to other plasmids or chromosomes, or they may be found on integrons, which have loci downstream of strong promoters at which resistance genes may insert by site-specific recombination to be expressed at high levels'' (Ref. 4 at p. 2820; Ref. 52). It is largely for this reason that FDA is proposing to include the entire *Enterobacteriaceae* family in the list of qualifying pathogens: With each increase in resistance rates seen in one genus or species, increases in antimicrobial resistance may also occur in other pathogens in the family. It is unsurprising, then, that the proportion of drug-resistant, versus drug-susceptible, *Enterobacteriaceae* infections has increased in the past several years (see, e.g., Refs. 53 and 54). For example, a March 2013 CDC Vital Signs report documented an increase in the percentage of *Enterobacteriaceae* that were non-susceptible to carbapenems, from one to four percent in the past decade (Ref. 136).

Infections with drug-resistant strains of *Enterobacteriaceae* also result in increased rates of morbidity and mortality when compared with drug-susceptible strains of the same pathogens. In one study, the mortality rate for patients with carbapenem-resistant *K. pneumoniae* infections was 48 percent—nearly double the 26 percent mortality rate for patients with carbapenem-susceptible *K. pneumoniae* infections (Ref. 55). These differential outcomes are of particular concern, because the proportion of patients with drug-resistant versus drug-susceptible *Enterobacteriaceae* infections has increased over the past several years (see, e.g., Refs. 5 and 54).

There are a limited number of drugs with antibacterial activity for infections with multiple-drug-resistant *Enterobacteriaceae.* This means that clinicians may not always be successful in selecting an appropriate initial antibacterial drug for treatment before the availability of the results of *in vitro* antibacterial drug susceptibility testing (Ref. 55 at pp. 1104–1105 (''Our study suggests that [polymyxins, tigecycline, and aminoglycosides], alone or in combination, may not be reliably effective in the treatment of carbapenem-resistant *K. pneumoniae* infection and that newer antimicrobial agents with improved clinical activity against carbapenem-resistant *K. pneumoniae* are needed.'')). Furthermore, some last-line therapies come with different and potentially more severe adverse effects (e.g., renal toxicity) than the drugs to which many *Enterobacteriaceae* have become resistant (see, e.g., Ref. 56).

For the reasons described previously, FDA believes that *Enterobacteriaceae* has the potential to pose a serious threat to the public health, and FDA is proposing to include the *Enterobacteriaceae* family in its list of qualifying pathogens.

H. Enterococcus Species

Species in the genus *Enterococcus* are gram-positive bacteria that normally colonize the human gastrointestinal tract (Ref. 4 at p. 2643). Enterococci can cause serious disease, including bacteremia or endocarditis; *E. faecalis*

and *E. faecium* are most commonly responsible for enterococcal infections and *E. gallinarum* also has been identified as an infective agent (see Ref. 4 at pp. 2643–2647). Enterococci have been designated by the Infectious Disease Society of America as one of six highly problematic drug-resistant organisms (the so-called ''ESKAPE'' pathogens), which ''currently cause the majority of US hospital infections and effectively 'escape' the effects of antibacterial drugs.'' (Refs. 5 and 6). Although some enterococcal isolates have intrinsic resistance, other isolates have acquired resistance either from selective antibacterial pressures or from transfer of genetic resistance mechanisms from one bacterium to another, including from non-*Enterococcus* species (see, e.g., Ref. 4 at pp. 2647–2651; see also Ref. 57).

Enterococcus infections have been reported as the second most common cause of hospital-acquired infection in the United States from 1986 to 1989 (Ref. 58). Among 5,484 *E. faecium* infections associated with healthcare reported to CDC's NHSN between 2009 and 2011, approximately 80 percent were resistant to vancomycin; in this same report among 3,314 *E. faecalis* healthcare-associated infections, approximately 9 percent were resistant to vancomycin (Ref. 132, Table 7).

Enterococci infections, including infections caused by enterococci that are drug-resistant (e.g., vancomycin-resistant enterococci or VRE), are often nosocomial infections. Enterococci isolates can be resistant to multiple antibacterial drugs; in fact, *Enterococcus faecium* resistant to linezolid and resistant to vancomycin have been isolated from patients (Ref. 59), and isolates resistant to multiple antibacterial drugs were identified in a global surveillance program (see, e.g., Ref. 60). Patients with bacteremia due to VRE had an increased mortality when compared to patients who had drug-susceptible enterococcal bacteremia (Refs. 61 and 62).

In sum, for the reasons described previously—and particularly because of the increasing threat that drug-resistant enterococci pose to the public health—FDA believes that *Enterococcus* species have the potential to pose a serious threat to public health, and FDA is proposing to include *Enterococcus* species in its list of qualifying pathogens.

I. Mycobacterium tuberculosis Complex

M. tuberculosis, the bacterium that causes tuberculosis (TB), is a major global public health burden (see generally, Ref. 64). *M. tuberculosis* usually affects the lungs (pulmonary TB), but *M. tuberculosis* can affect any part of the body such as the kidney, spine, or brain (extrapulmonary TB) (Ref. 65). If TB is not properly treated, it can be fatal (see generally, Ref. 64 and Ref. 65). *M. tuberculosis* is expelled into the air when a person with TB of the lungs or throat coughs, sneezes, speaks, or sings (Ref. 65). People nearby may breathe in the organisms and become infected. *M. tuberculosis* can remain in the air for several hours, depending on the environment (Ref. 65). Factors essential for the spread of the organism are proximity and duration of contact and infectiousness of the source patient (Ref. 4 at pp. 3132, 3134). There are at least 7 species of the genus *Mycobacterium* that also cause disease similar to pulmonary tuberculosis, for example, *M. bovis, M. africanum,* and *M. microti,* among other species (Ref. 137).

Latent *M. tuberculosis* is found in one-third of the world's population (Ref. 66). In 2011, there were an estimated 8.7 million new cases and 1.4 million deaths associated with TB (Ref. 64). More than 10,000 new cases of TB were reported in 2011 in the United States (Ref. 67). Mortality figures from CDC reveal that 529 persons died in the United States from tuberculosis in 2009 (Ref. 67).

For *M. tuberculosis,* the primary mechanism of drug resistance is spontaneous chromosomal mutations, which can be amplified in the setting of inappropriate or interrupted therapy (monotherapy and combination therapy) or poor patient adherence to therapy (Ref. 68 at p. 1321). Subsequent transmission of drug-resistant *M. tuberculosis* will exacerbate the public health problem (Ref. 68). Mobile genetic elements, such as plasmids or transposons, do not appear to mediate drug resistance in *M. tuberculosis* (Ref. 68 at p. 1321). Thus, the increase in drug-resistant tuberculosis that is seen globally (see generally, Ref. 64) is a public health problem driven by inappropriate, interrupted, or poor adherence to therapy among persons being treated for TB (primary resistance), and subsequent transmission of drug-resistant *M. tuberculosis* from person to person (secondary resistance) (Ref. 68).

Isolates of *M. tuberculosis* resistant to isoniazid and rifampin, the two most important first-line antibacterial drugs used in the treatment of active TB disease, are referred to as multi-drug resistant (MDR) strains (Ref. 65). Extensively drug resistant (XDR) TB is resistant to isoniazid and rifampin, as well as two second-line drug classes (injectable agents and fluoroquinolones) (Ref. 65). Results from a multinational survey showed that 20 percent of *M. tuberculosis* isolates were MDR, and 2 percent were also XDR (Ref. 69). Resistance mechanisms are well-established for most drugs used to treat tuberculosis (Ref. 70), and drug resistant strains of tuberculosis can be transmitted from person to person, as evidenced in a 1991–1992 outbreak investigation in New York City (Ref. 71).

An epidemiological evaluation by CDC of pulmonary tuberculosis among patients in the United States found that mortality rates were higher for patients with XDR tuberculosis compared with those with MDR tuberculosis (35 percent vs. 24 percent, respectively), with the lowest mortality (10 percent) observed in patients with drug-susceptible tuberculosis (Ref. 72 at p. 2157). The authors of this report concluded that, ''[t]he emergence of XDR [tuberculosis] globally has raised concern about a return to the pre-antibiotic era in [tuberculosis] control, since XDR [tuberculosis] cases face limited therapeutic options and consequently have poor treatment outcomes and high mortality,'' (Ref. 72 at p. 2158).

For the reasons stated previously, FDA believes that *M. tuberculosis* complex has the potential to pose a serious threat to public health, and FDA is proposing to include *M. tuberculosis* complex in the list of qualifying pathogens.

J. Neisseria gonorrhoeae

N. gonorrhoeae is a nonmotile, gram-negative bacterium that can infect the mucous membrane of the urethra and cervix, as well as the rectum, oropharynx, and conjunctivae (Ref. 4 at p. 2753). The pathogen can be transmitted sexually (Ref. 73), as well as vertically from mother to newborn during delivery (Ref. 74). Gonococcal infections can cause complications, such as pelvic inflammatory disease, ectopic pregnancy, epididymitis, ophthalmitis, and endocarditis (Ref. 4 at p. 2753). Gonorrhea is the second most commonly reported notifiable disease in the United States: Over 300,000 cases of gonorrhea are reported annually (Ref. 73). However, many infections are probably undetected and unreported: CDC estimates that more than 800,000 new gonococcal infections occur annually in the United States (Ref. 75). Although the gonorrhea rate is low compared with historical trends, the rate increased during 2009–2011 (Ref. 73).

N. gonorrhoeae can acquire antibacterial drug resistance by

spontaneous chromosomal mutations arising from endogenous flora, or resistance can be acquired by transfer of genetic information from other bacteria by, for example, a plasmid-mediated resistance mechanism (Ref. 76). The Gonococcal Isolate Surveillance Project (GISP) monitors trends in antimicrobial susceptibilities of *N. gonorrhoeae* strains in the United States (Ref. 73).[6] In 2011, 30.4 percent of isolates collected in the GISP were resistant to penicillin, tetracycline, ciprofloxacin, or a combination thereof (Ref. 73).

Since 2007, the cephalosporins have been the only antibacterial drug class recommended by CDC for the first line treatment of gonorrhea (Ref. 77). On the basis of ongoing surveillance, in 2012, CDC changed its treatment guidelines to recommend dual therapy with intramuscular ceftriaxone (instead of the previously-recommended orally-administered antibacterial drug), with either azithromycin or doxycycline added not only for treatment of coinfection with *Chlamydia trachomatis,* but also to ''potentially delay emergence and spread of resistance to cephalosporins'' in *N. gonorrhoeae* (Ref. 77). This is the only remaining recommended first-line treatment regimen (Ref. 77). Reduced susceptibility of gonococcal strains to ceftriaxone has also been observed (Ref. 73). Indeed, there is a growing concern that *N. gonorrhoeae* may become resistant to all available antibacterial drugs (Ref. 78). Significantly, ''[u]nsuccessful treatment of gonorrhea with oral cephalosporins, such as cefixime, has been identified in East Asia, beginning in the early 2000s, and in Europe within the past few years. Ceftriaxone-resistant isolates have been identified in Japan (2009), France (2010), and Spain (2011)'' (Ref. 153, internal references omitted). The GISP reported that cephalosporin-resistance may now be emerging in the United States (Ref. 153).

For the reasons stated previously—particularly the increase in antibiotic resistant strains of gonorrhea together with the limited number of effective antibiotics for treatment of *N. gonorrhoeae*—FDA believes that *N. gonorrhoeae* has the potential to pose a serious threat to public health, and FDA is proposing to include *N. gonorrhoeae* on the list of qualifying pathogens.

[6] The GISP was established by the CDC in 1986 to monitor trends in antimicrobial susceptibilities of strains of *N. gonorrhoeae* in the United States to establish a rational basis for the selection of gonococcal therapies.

K. Neisseria meningitidis

N. meningitidis is an aerobic, gram-negative, fastidious diplococcus that is a leading cause of bacterial meningitis and sepsis, and can cause other serious infectious diseases, such as pneumonia, arthritis, otitis media, and epiglottitis (Ref. 79). *N. meningitidis* can be readily transmitted directly from person to person through close or prolonged contact via respiratory or throat droplets (e.g., kissing, sneezing, coughing, or living in close quarters) (Ref. 80).

Meningococcal disease is a global public health concern that remains endemic in the United States, with large epidemics of invasive disease occurring in Africa, New Zealand, and Singapore (Ref. 4 at p. 2740). Nasopharyngeal carriage of *N. meningitidis* is a precursor to disease (Ref. 4 at p. 2740), and while the majority of carriers do not develop disease, the World Health Organization estimates that, at any given time, 10 to 20 percent of the population carries *N. meningitidis* in their nasopharynx (Ref. 80). In the United States, the incidence rate is 0.15 to 0.5 per 100,000 persons (see Refs. 81 and 82). Mortality rates vary by the type of infectious disease caused by *N. meningitidis,* with a 40 percent mortality rate among patients with meningococcemia (Ref. 79), and a 13 percent mortality rate among children and adolescents with bacterial meningitis (Ref. 4 at p. 2741). Morbidity following infection with *N. meningitidis* can be substantial, including hearing loss, neurologic sequelae, and loss of limbs from amputation (Ref. 83 at p. 773).

N. meningitidis is believed to acquire resistance from the wider gene pool of other *Neisseria* species (Ref. 84 at p. 890) and through point mutations. Antibacterial drug resistance was identified as a concern in *N. meningitidis* almost 2 decades ago, with a demonstration that resistance to commonly-used antibacterial drugs were increasing in incidence, and the identification of some isolates with beta-lactamase production (i.e., the production of enzymes that cause bacteria to be resistant to beta-lactam antibacterial drugs), with the author concluding that ''this finding is of great concern,'' (Ref. 85 at p. S98). Invasive meningococcal diseases caused by isolates with reduced susceptibility to penicillin were first reported in the 1980s in the United Kingdom, Spain, and South Africa, and are now identified worldwide (Ref. 139 at p. 1016). Some countries have reported a rise in the prevalence of meningococci with reduced susceptibility to penicillin (see, e.g., Refs. 85 and 141). Case reports and studies suggest that reduced susceptibility to common antibacterial treatments used for meningococcal infection results in poorer health outcomes (Ref. 83 at p. 776). For example, a Spanish study of isolates from 1988 to 1992 found that patients with strains that had decreased drug susceptibility had higher rates of morbidity and mortality (Ref. 83 at p. 776; Ref. 149 at p. 28). Other sporadic cases of invasive *N. meningitidis* with reduced susceptibility to antibacterial drugs have been reported worldwide (see, e.g., Refs. 142 and 143). The identification of *N. meningitidis* isolates that display elevated mutability suggests an increased capacity to develop resistance, in addition to possible enhancement of transmission (see, e.g., Ref. 144).

The detection of *N. meningitidis* with reduced susceptibility or resistance to antibacterial drugs has broad and serious implications for public health, not only for treatment of patients with invasive disease, but also when considering the use of chemoprophylaxis in order to prevent cases of invasive meningococcal disease among close contacts (see, e.g., Refs. 139,142, and 143). In sum, for the reasons described previously—particularly because of the potential for higher morbidity and mortality associated with drug-resistant meningococcal infections—FDA believes that *N. meningitidis* has the potential to pose a serious threat to public health, and FDA is proposing to include *N. meningitidis* in the list of qualifying pathogens.

L. Non-Tuberculous Mycobacteria Species

Non-tuberculous *mycobacterium* (NTM) comprises several species of bacterium, including *Mycobacterium avium* complex, *M. kansasii,* and *M. abscessus* (Ref. 4 at p. 3191; Ref. 86). Other species known to cause disease include *M. fortuitum, M. chelonae, M. marinum,* and *M. ulcerans* (Ref. 4 at p. 3191). NTM are widely distributed in the environment and can be found in soil, water, plants, and animals (Ref. 4 at p. 3191). Transmission is not communicable, and it appears to occur from environmental exposure to or inhalation of the pathogen (Ref. 87 at p. 370). NTM causes many serious and life-threatening diseases, including pulmonary disease, catheter-related infections, lymphadenitis, skin and soft tissue disease, joint infections, and, in immunocompromised individuals, disseminated infection (Ref. 4 at p. 3192).

NTM infections appear to be increasing in the United States (see, e.g., Refs. 88 and 89). A recently published study of Medicare patients showed an increasing prevalence of pulmonary NTM across all regions in the United States (Ref. 89 at p. 882). The authors concluded that the annual prevalence significantly increased from 1997 to 2007 from 20 to 47 cases per 100,000 persons, respectively, or an 8.2 percent per year increase in prevalence among the Medicare population. Similarly, a population-based study in Ontario, Canada suggests an increase in the frequency of NTM infections from 9.1 per 100,000 persons in 1997 to 14.1 per 100,000 persons in 2003, resulting in an average annual increase of 8.4 percent (Ref. 90).

Antibacterial drug resistance in these organisms is ''the result of a highly complex interplay between natural resistance, inducible resistance and mutational resistance acquired during suboptimal drug exposure and selection,'' (Ref. 91 at p. 150). Treatment for NTM lung infections requires long courses of therapy, often 18 to 24 months or longer (Ref. 92 at p. 123). Because NTM is resistant to many antibacterial drugs currently available, infections caused by NTM can be difficult to treat. While there are no data from NTM isolates that indicate increasing antibacterial drug resistance, the incidence of NTM infections with intrinsic antibacterial resistance is increasing (Ref. 91). This observation raises concerns that resistant NTM may be responsible for a disproportionate share of clinical infection.

For the reasons stated previously, FDA believes that non-tuberculous mycobacteria species has the potential to pose a serious threat to public health and, FDA is proposing to include non-tuberculous mycobacteria species on the list of qualifying pathogens.

M. Pseudomonas Species

Species of the *Pseudomonas* genus are gram-negative bacteria that can cause serious infections (Ref. 4 at p. 3025). This is particularly true of *P. aeruginosa,* which ''accounted for 18.1% of hospital-acquired pneumonias and a significant percentage of urinary tract infections (16.3%), surgical site infections (9.5%), and bloodstream infections (3.4%)'' in the United States. ICUs in 2003 (Ref. 4 at p. 2837 (citing Ref. 151)). *P. aeruginosa* is ''among the top five causes of nosocomial bacteremia, and severe infection can lead to sepsis'' (Ref. 4 at p. 2847). It can grow in many environments (e.g., soil, water, and plants) (Ref. 4 at p. 2835) including moist hospital environments (e.g., showers, ventilators, mop water), and some healthy people have *P. aeruginosa* as a colonizing bacterium in their skin, throat, nose, or stool (Ref. 4 at p. 2836). *P. aeruginosa* is among the so-called ''ESKAPE'' pathogens, which ''currently cause the majority of US hospital infections and effectively 'escape' the effects of antibacterial drugs.'' (Refs. 5 and 6). *P. aeruginosa* pulmonary infection among patients with CF is associated with a more rapid decline in lung function (Ref. 18 (internal citation omitted)).

''*P. aeruginosa* now carries multiple genetically-based resistance determinants, which may act independently or in concert with others'' (Ref. 4 at p. 2856 (citing Ref. 152)). Furthermore, *P. aeruginosa* is known for its ability to ''acquire'' resistance mechanisms (see, e.g., Ref. 9). *P. aeruginosa* has been noted to develop resistance during antibacterial drug therapy even when the results of in vitro susceptibility show that the bacterium is fully susceptible when initially exposed to the antibacterial drug. (see, e.g., Ref. 93 (internal citations omitted); see also, e.g., Ref. 4 at p. 2855 (noting that in patients with *P. aeruginosa* endocarditis there is a ''likelihood of the patient's becoming resistant to therapy even if there is initially bloodstream sterilization'')). Resistant *P. aeruginosa* strains may be transmitted from person to person, or via contamination in the environment (see, e.g., Ref. 94). In a recent report from CDC's NHSN, approximately 8 percent of all healthcare-associated infections were caused by *P. aeruginosa;* among the 6,111 *P. aeruginosa* infections that were reported, approximately 25 percent were resistant to carbapenems and approximately 15 percent showed resistance in at least 3 different classes of antibacterial drugs (i.e., ''multi-drug resistant'') (Ref. 132 at Table 7).

Morbidity and mortality rates for *P. aeruginosa* infection are generally recognized as being high (see, e.g., Ref. 93 (internal citations omitted)), and infection with drug-resistant strains may have a negative effect on clinical outcomes, including an association with higher mortality (Ref. 93). Pneumonia and bloodstream infections due to drug-resistant *P. aeruginosa* have been associated with higher mortality rates in comparison to the same infections due to drug-susceptible *P. aeruginosa* (Ref. 10 at pp. 32–33, Tables 2 and 3). Although *Pseudomonas* non-*aeruginosa* infections are rare, pathogenic members of the *Pseudomonas* genus can cause serious infections and can show resistance to multiple antibacterial drugs (Ref. 95).

For the reasons described previously—including the prevalence of *Pseudomonas* infections (particularly *P. aeruginosa*), the associated high morbidity and mortality rates, the increasing antibacterial drug resistance, and the fact that the last-line antibacterial drug treatments (required to treat *Pseudomonas* infections because of its resistance to multiple classes of antibacterial drugs) often have different or more serious adverse effects—FDA believes that *Pseudomonas* has the potential to pose a serious threat to public health, and FDA is proposing to include *Pseudomonas* species in its list of qualifying pathogens.

N. Staphylococcus aureus

Staphylococcus aureus is a gram-positive bacterium that causes a variety of serious infectious diseases (Ref. 4 at p. 2543). *S. aureus* infections commonly result in skin or soft tissue infections (see, e.g., Ref. 4 at pp. 2543, 2559), and may result in more life-threatening infections (e.g., pneumonia, bloodstream), often due to infection via catheters, ventilators, or other medical devices or procedures (Ref. 96). *S. aureus* is one of the most common bacterial pathogens in hospital-acquired infections, and resistance rates for *S. aureus* have been increasing (see, e.g., Refs. 3 and 97). In addition, in the first decade of the 21st century, resistant strains of *S. aureus* (e.g., methicillin-resistant *S. aureus* or MRSA) that emerged in the community and in some hospitals are now responsible for the majority of *S. aureus* infections among outpatients (Ref. 98). In the United States in 2005, the rate of invasive MRSA infections was approximately 31.8 infections per 100,000 people (Ref. 99). *S. aureus* is also a member of the so-called ''ESKAPE'' pathogens, which ''currently cause the majority of U.S. hospital infections and effectively 'escape' the effects of antibacterial drugs.'' (Refs. 5 and 6). Reports of rapid increases in the proportion of patients hospitalized due to infections caused by MRSA were largely due to increases in skin and soft tissue infections caused by MRSA acquired in the community setting (Ref. 145). The national burden of disease due to MRSA on an outpatient basis is substantial in the United States, with an estimated 51,290 infections reported in 2010 (Ref. 146).

''*S. aureus* has developed resistance to virtually all antibiotic classes available for clinical use,'' as demonstrated by a combination of in vivo and in vitro data (Ref. 4 at p. 2558). In fact, numerous antibacterial resistance mechanisms have been documented in *S. aureus,* including the

transmission of resistance that can occur via plasmids shared between bacteria, or even transfer of resistance mechanisms from different genera of bacteria (see Ref. 100).

Patients with drug-resistant *S. aureus* infections appear to have higher mortality when compared to patients with drug-susceptible *S. aureus* infection (Ref. 10, Table 3 (showing a case fatality rate for patients with susceptible *S. aureus* bloodstream infections of 74/284 (26 percent) and a case fatality rate for patients with resistant *S. aureus* bloodstream infections of 65/171 (38 percent)). Although infections caused by vancomycin-resistant *S. aureus* (VRSA) have been very rare (see, e.g., Ref. 101), the fact that VRSA has been observed at all underscores that antibacterial drug use can exert selective pressures on *S. aureus,* effectively creating antibacterial drug resistance. When patients have infection with drug-resistant *S. aureus,* the limited options for therapy may result in concerns about the feasibility of certain therapies (e.g., some treatments involve intravenous administration, which might require hospital admission) or different adverse effect profiles that may negatively affect patients' lives (Ref. 102). It is clear, then, that drug-resistant *S. aureus* poses an increasingly serious threat to public health.

Therefore, for the reasons described previously, FDA believes that *S. aureus* has the potential to pose a serious threat to public health, and FDA is proposing to include *S. aureus* in its list of qualifying pathogens.

O. Streptococcus agalactiae

Infections caused by *S. agalactiae* (Group B *streptococcus* or GBS) are considered a major public health concern, particularly because the organism causes meningitis and sepsis in newborns due to transmission from the mother during labor and delivery (see generally, Refs. 103, 104, and 105). Maternal intrapartum antibacterial prophylaxis is recommended for pregnant women colonized with GBS, and resistance to antibacterial drugs commonly prescribed for prophylaxis is increasing (Ref. 103), thus having the potential to limit options for prophylaxis in this population. The most common diseases caused by GBS in adults are bloodstream infections, pneumonia, endocarditis, skin and soft-tissue infections, and bone and joint infections (see generally, Ref. 4 at pp. 2655–2661; Ref. 104). GBS infections can also result in other public health concerns, such as miscarriages, stillbirths, and preterm deliveries (Ref. 105).

Over the past two decades, the incidence rates of GBS have increased twofold to fourfold in nonpregnant adults, ''most of whom have underlying medical conditions or are 65 years of age or older,'' (Ref. 4 at p. 2655). The rate of invasive disease is approximately 7 per 100,000 nonpregnant adults, with the highest rate in adults aged 65 years and older at 20–25 per 100,000 persons (Ref. 106). Case-fatality rates range from 5 to 25 percent in nonpregnant adults (Ref. 4 at p. 2659).

Resistance to antibacterial drugs has emerged in GBS, with most mechanisms believed to be an inducible chromosomally-mediated resistance that can occur due to selective pressures of antibacterial drugs (Ref. 103). Recent epidemiological surveillance shows that resistance to beta-lactam antibacterial drugs, the mainstay of treatment and prevention of GBS infections, has not been identified in the United States (Ref. 107). However, there is the potential in GBS of chromosomally-mediated mechanisms conferring decreased susceptibility to beta-lactam antibacterial drugs (Ref. 108). In addition, the potential for the spread of beta-lactamases via plasmid or other genetic transfer mechanisms (see Ref. 109) to GBS will continue to be a grave concern for public health, given the pivotal role of beta-lactam antibacterial drugs for treatment and prevention of GBS infections.

CDC and researchers from other countries have described patterns of reduced susceptibility and resistance of GBS strains to common antibacterial drugs, including penicillin, macrolides, and clindamycin (see, e.g., Refs. 110 and 111). Because GBS is a common infectious disease and resistance to antibacterial drugs has been observed, it stands to reason that resistance may increase in the future.

For the foregoing reasons, FDA believes that *S. agalactiae* has the potential to pose a serious threat to public health, and FDA is proposing to include *S. agalactiae* in the list of qualifying pathogens.

P. Streptococcus pneumoniae

S. pneumoniae is a gram-positive bacterium that causes bacterial meningitis, bacteremia, respiratory tract infections including pneumonia, and otitis media (see, e.g., Refs. 112 and 113). *S. pneumoniae* can colonize the nasopharynx region, and transmission from person to person, via close contact by respiratory droplets, is thought to be common (Ref. 112). Although not all persons with *S. pneumoniae* colonization go on to develop invasive disease, colonization is a risk factor for disease.

Outbreaks of invasive pneumococcal disease are known to occur in closed populations, such as nursing homes, childcare institutions, prisons, or other institutions (Ref. 112). Invasive disease from *S. pneumoniae* is a major cause of illness and death in the United States, with an estimated 43,500 cases and 5,000 deaths in 2009 (Ref. 114). In the United States, among elderly adults hospitalized with invasive pneumonia, the mortality rate is approximately 14 percent (Ref. 115). Resistance to commonly used antibacterial drugs for treatment of *S. pneumoniae* has been observed: Surveillance studies conducted in the United States between 1994 and 2007 showed that 9 to 24 percent of pneumococci were resistant to at least 3 classes of antibiotics (Ref. 113).

High rates of antibacterial drug resistance in *S. pneumoniae* have been documented worldwide. For example, *S. pneumoniae* resistance to commonly-used antibacterial drugs has been established for several decades, with incidence of resistance to penicillin in the United States approaching 40 percent in the late 1990s (Ref. 116). In China, approximately 96 percent of all recent *S. pneumoniae* isolates were resistant to erythromycin, and multidrug resistance was prevalent in many Asian countries (Ref. 117). In certain European countries, the proportion of isolates with resistance to multiple antibacterial drugs increased from 2006 to 2009 (e.g., in Bulgaria, resistance to penicillin increased from approximately 7 percent of isolates in 2006 to approximately 37 percent of isolates in 2009) (Ref. 118 at pp. 20, 23). In the United States, some children with middle ear infection had strains of *S. pneumoniae* that were resistant to all antibacterial drugs that have an FDA-approved label for treatment of acute bacterial otitis media in children (Ref. 147). Development of resistance by *S. pneumoniae* strains to macrolide antibacterial drugs and the closely-related azolide drugs, which has been increasing in incidence, can be due to efflux-mediated mechanisms or target modifications caused by a ribosomal methylase (Ref. 148). It is speculated that increased use of macrolide antibacterial drugs may have exerted pressures in which resistance mechanisms spontaneously occurred (Ref. 148).

For the reasons described previously, including that current strains of pneumococcal disease are associated with increased resistance to commonly

used antibacterial drugs, FDA believes that *S. pneumoniae* has the potential to pose a serious threat to public health, and FDA is proposing to include *S. pneumoniae* in the list of qualifying pathogens.

Q. Streptococcus pyogenes

S. pyogenes (group A *streptococcus* or GAS) is a gram-positive bacterium that causes acute pharyngitis, in addition to other serious infectious diseases, such as necrotizing fasciitis and toxic shock syndrome (see generally, Ref. 4 at pp. 2593–2596). GAS is likely transmitted from person to person via respiratory droplets. Close personal contact, such as in schools, appears to favor spread of the organism (Ref. 4 at p. 2595).

A study published in 2003 found that approximately 1.8 million people in the United States are diagnosed with streptococcal pharyngitis annually (Refs. 119 and 120). Although streptococcal pharyngitis is typically a mild disease, in rare cases, it can result in severe post-infectious complications (see generally, Ref. 121). Though the annual incidence of invasive GAS disease is estimated to be approximately 4.3 per 100,000 persons per year, the rate of mortality associated with invasive GAS infections is high, with an estimate of 0.5 per 100,000 persons per year (Ref. 122). This means that in the United States, each year over 13,000 people are estimated to acquire an invasive GAS infection annually, and over 1,500 people are estimated to die from an invasive GAS infection (Ref. 122).

For over 80 years, GAS isolates have remained susceptible to penicillin, though reports of resistance to other antibacterial drugs have emerged in GAS, primarily by chromosomally mediated mechanisms (see generally, Refs. 123 and 124). However, recently identified genes in GAS encode for several penicillin-binding proteins, but a reason for why these genes are not expressed has yet to be determined (Ref. 123). In addition, there is an ongoing concern that transfer of antibacterial resistance to GAS by plasmid or other genetic transfer might occur at some point in the future (Ref. 109). Indeed, microbiology laboratories are encouraged to continue to perform in vitro susceptibility testing on all GAS isolates in order to monitor for the possibility of resistance (Ref. 123). Thus, given the pivotal role of the beta-lactam antibiotic penicillin in the treatment of GAS, any resistance that would occur in the future would be of great concern for public health. Antibacterial resistance in *S. pyogenes* to commonly used drugs has been reported in many countries, including the United States (Ref. 4 at p. 2599). Resistance to macrolide antibiotics and the closely related azolide group is common and poses a threat because these drugs are often used in penicillin-allergic patients (see Ref. 157). Resistance to clindamycin, a drug used for treatment of patients with necrotizing fasciitis, has also emerged (see Ref. 157).

For the reasons described previously, including the high morbidity and mortality associated with invasive infections, the frequency of less severe infections, the existing resistance to some commonly used agents and the possibility for an increase in resistant strains, GAS infections have the potential to pose a serious threat to public health and, FDA is proposing to include *S. pyogenes* in the list of qualifying pathogens.

R. Vibrio cholerae

Vibrio cholerae is a gram-negative bacterium (Ref. 4 at p. 2777) that can cause cholera, an acute diarrheal illness that can lead to severe dehydration (Ref. 125). Although cholera is found mainly in developing countries with poor sanitation and unsafe water supplies, in the United States, disease may occur in travelers returning from such countries or, more rarely, in those who have eaten contaminated food (see, e.g., Refs. 125 and 126). *V. cholerae* has the potential to cause pandemics and ''the ability to remain endemic in all affected areas'' (Ref. 4 at p. 2778 (internal citation omitted)), possibly due to the fact that infected people may shed the bacteria for several months after infection (Ref. 4 at p. 2779).

Antibacterial drug resistance in cholera-causing strains of *V. cholerae* has increased between 1990 and 2000 in U.S. patients with both domestically- and internationally-acquired infections (Ref. 126), and antibacterial drug resistance in *V. cholerae* is still increasing generally (Refs. 126, 127, 128, and 129). ''Antimicrobial drug resistance in *Vibrio* [species] can develop through mutation or through acquisition of resistance genes on mobile genetic elements, such as plasmids, transposons, integrons, and integrating conjugative elements,'' or ICEs (Ref. 127). ICEs in particular ''commonly carry several antimicrobial drug resistance genes and play a major role in the spread of antimicrobial drug resistance in *V. cholerae*'' (Ref. 127 at p. 2151; Ref. 130).

Cholera-causing strains of *V. cholerae* may not cause disease in all people (Ref. 131). However, an estimated 10 percent of those infected with the O1 serogroup will develop a severe enough form of the illness that they need treatment (Ref. 131). Rehydration therapy is the most critical component of cholera treatment (see, e.g., Ref. 140). Approximately 25 to 50 percent of untreated cholera cases may prove fatal (Ref. 125). Antibiotic therapy is recommended for severely ill patients. It stands to reason that the risk of mortality in particular is likely to increase for drug-resistant *V. cholerae* infections among patients with limited treatment options.

For the reasons described previously, including the epidemic potential of toxigenic *V. cholerae* strains, as well as the ease with which this pathogen may be transmitted, this bacterium has the potential to pose a serious threat to public health, and, FDA is proposing to include *V. cholerae* in the list of qualifying pathogens.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Economic Impact

A. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule would not impose direct costs on any entity, regardless of size, but rather would clarify certain types of pathogens for which the development of approved treatments might result in the awarding of QIDP designation and exclusivity to sponsoring firms, FDA proposes to certify that the final rule would not have

a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $139 million, using the most current (2011) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

B. Background

Antibacterial research and development has reportedly declined in recent years. A decrease in the number of new antibacterial products reaching the market in recent years has led to concerns that the current drug pipeline for antibacterial drugs may not be adequate to address the growing public health needs arising from the increase in antibiotic resistance. A number of reasons have been cited as barriers to robust antibacterial drug development including smaller profits for short-course administration of antibacterial drugs compared with long-term use drugs to treat chronic illnesses, challenges in conducting informative clinical trials demonstrating efficacy in treating bacterial infections, and growing pressure to develop appropriate limits on antibacterial drug use.

One mechanism that has been used to encourage the development of new drugs is exclusivity provisions which provide for a defined period during which an approved drug is protected from submission or approval of certain potential competitor applications. By securing additional guaranteed periods of exclusive marketing, during which a drug sponsor would be expected to benefit from associated higher profits, drugs that might not otherwise be developed due to unfavorable economic factors may become commercially attractive to drug developers.

In recognition of the need to stimulate investments in new antibiotic drugs, Congress enacted the GAIN title of FDASIA to create an incentive system. The primary framework for encouraging antibiotic development became effective on July 9, 2012, through a self-implementing provision that authorizes FDA to designate human antibiotic or antifungal drugs that treat ''serious or life-threatening infections'' as QIDPs. With certain limitations set forth in the statute, a sponsor of an application for an antibiotic or antifungal drug that receives a QIDP designation gains an additional 5 years of exclusivity to be added to certain exclusivity periods for that product. Drugs that receive a QIDP designation are also eligible for designation as a fast-track product and an application for such a drug is eligible for priority review.

C. Need for and Potential Effect of the Regulation

Between July 9, 2012, when the GAIN title of FDASIA went into effect, and January 31, 2013, FDA granted 11 QIDP designations. As explained previously, the statutory provision that authorizes FDA to designate certain drugs as QIDPs is self-implementing, and inclusion of a pathogen on the list of ''qualifying pathogens'' does not determine whether a drug proposed to treat an infection caused by that pathogen will be given QIDP designation. However, section 505E(f) of the FD&C Act, added by the GAIN title of FDASIA, requires that FDA establish a list of ''qualifying pathogens.'' This proposed rule is intended to satisfy that obligation, as well as the statute's directive to make public the methodology for developing such a list of ''qualifying pathogens.'' The proposed rule identifies 18 ''qualifying pathogens,'' including those provided as examples in the statute, which FDA has concluded have ''the potential to pose a serious threat to public health'' and proposes to include on the list of ''qualifying pathogens.''

As previously stated, this proposed rule would not change the criteria or process for awarding QIDP designation, or for awarding extensions of exclusivity periods. That is, the development of a treatment for an infection caused by a pathogen included in the list of ''qualifying pathogens'' is neither a necessary nor a sufficient condition for obtaining QIDP designation, and, as stated in section 505E(c) of the FD&C Act, not all applications for a QIDP are eligible for an extension of exclusivity. Relative to the baseline in which the exclusivity program under GAIN is in effect, we anticipate that the incremental effect of this rule would be negligible.

To the extent that this rule causes research and development to shift toward treatments for infections caused by pathogens on the list and away from treatments for infections caused by other pathogens, the opportunity costs of this rule would include the forgone net benefits of products that treat or prevent pathogens not included in the list, while recipients of products to treat infections caused by pathogens on the list would receive benefits in the form of reduced morbidity and premature mortality. Sponsoring firms would experience both the cost of product development and the economic benefit of an extension of exclusivity and of potentially accelerating the drug development and review process with fast-track status and priority review. If this rule induces greater interest in seeking QIDP designation than would otherwise occur, FDA would also incur additional costs of reviewing applications for newly-developed antibacterial or antifungal drug products under a more expedited schedule.

Given that the methodology for including a pathogen in the list of ''qualifying pathogens'' was developed with broad input, including input from industry stakeholders and the scientific and medical community involved in anti-infective research, we expect that the pathogens listed in this proposed rule reflect not only current thinking regarding the types of pathogens which have the potential to pose serious threat to the public health, but also current thinking regarding the types of pathogens that cause infections for which treatments might be eligible for QIDP designation. To the extent that there is overlap between drugs designated as QIDPs and drugs developed to treat serious or life-threatening infections caused by pathogens listed in this proposed rule, this proposed rule would have a minimal impact in terms of influencing the volume or composition of applications seeking QIDP designation, compared to what would otherwise occur in the absence of this rule.

VIII. Paperwork Reduction Act

FDA concludes that this proposed rule does not contain a ''collection of information'' that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). This proposed rule interprets some of the terms used in section 505E of the FD&C Act and proposes ''qualifying pathogen'' candidates. Inclusion of a pathogen on the list of ''qualifying pathogens'' does not confer any information collection requirement upon any party, particularly because inclusion of a pathogen on the list of ''qualifying pathogens,'' and the QIDP designation process, are distinct processes with differing standards.

The QIDP designation process will be addressed separately by the Agency at a later date. Accordingly, the Agency will analyze any collection of information or

additional PRA-related burdens associated with the QIDP designation process separately.

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

X. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

XI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov*. (FDA has verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to Web sites after this document publishes in the **Federal Register**.)

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List of Subjects in 21 CFR Part 317

Antibiotics, Communicable diseases, Drugs, Health, Health care, Immunization, Prescription drugs, Public health.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 317 is proposed to be added to read as follows:

PART 317—QUALIFYING PATHOGENS

Sec.
317.1 [Reserved]
317.2 List of qualifying pathogens that have the potential to pose a serious threat to public health.

Authority: 21 U.S.C. 355E, 371.

§ 317.2 List of qualifying pathogens that have the potential to pose a serious threat to public health.

The term ''qualifying pathogen'' in section 505E(f) of the Federal Food, Drug, and Cosmetic Act is defined to mean any of the following:

(a) *Acinetobacter* species.
(b) *Aspergillus* species.
(c) *Burkholderia cepacia* complex.
(d) *Campylobacter* species.
(e) *Candida* species.
(f) *Clostridium difficile.*
(g) *Enterobacteriaceae.*
(h) *Enterococcus* species.
(i) *Mycobacterium tuberculosis* complex.
(j) *Neisseria gonorrhoeae.*
(k) *Neisseria meningitidis.*
(l) Non-tuberculous mycobacteria species.
(m) *Pseudomonas* species.
(n) *Staphylococcus aureus.*
(o) *Streptococcus agalactiae.*
(p) *Streptococcus pneumoniae.*
(q) *Streptococcus pyogenes.*
(r) *Vibrio cholerae.*

Dated: June 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13865 Filed 6–11–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2013–N–0568]

Physical Medicine Devices; Reclassification of Stair-Climbing Wheelchairs

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed administrative order to reclassify stair-climbing wheelchairs, a class III device, into class II (special controls) based on new information and subject to premarket notification, and to further clarify the identification.

DATES: Submit either electronic or written comments on this proposed order or on the draft guideline by September 10, 2013. See section XII for the proposed effective date of any final order that may publish based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2013–N–0568 by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

• *Mail/Hand Delivery/Courier (for paper or CD–ROM submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2013–N–0568. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rebecca Nipper, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1540, Silver Spring, MD 20993, 301–796–6527.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513(d) of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval.

Devices that were not in commercial distribution prior to May 28, 1976, (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807).

The Safe Medical Devices Act of 1990 (Pub. L. 101–629) changed the definition of class II devices from those for which a performance standard is necessary to provide reasonable assurance of safety and effectiveness to those for which there is sufficient information to establish special controls to provide such assurance. Special controls include performance standards.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended the device reclassification procedures under section 513(e) of the FD&C Act, changing the process from rulemaking to an administrative order. Prior to the issuance of a final order reclassifying a device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments to a public docket. The proposed reclassification order must set forth the proposed reclassification and a substantive summary of the valid scientific evidence concerning the proposed reclassification, including the public health benefits of the use of the device, and the nature and incidence (if known) of the risk of the device. (See section 513(e)(1)(A)(i) of the FD&C Act.) As required by section 513(b) of the FD&C Act, FDA intends to schedule a panel meeting to discuss the proposed reclassification prior to issuing a final order.

Section 513(e) of the FD&C Act provides that FDA may, by administrative order, reclassify a device based upon ''new information.'' FDA can initiate a reclassification under section 513(e) or an interested person may petition FDA. The term ''new information,'' as used in section 513(e) of the FD&C Act, includes information developed as a result of a reevaluation of the data before the Agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (See, *e.g., Holland-Rantos Co.* v. *United States Dep't of Health, Educ., & Welfare,* 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn* v. *Finch,* 422 F.2d 944 (6th Cir. 1970); *Bell* v. *Goddard,* 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available authority (see *Bell,* 366 F.2d at 181; *Ethicon, Inc.* v. *FDA,* 762 F.Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn* v. *Finch,* 422 F.2d at 951). Whether data before the Agency are old or new data, the ''new information'' to support reclassification under section 513(e) must be ''valid scientific evidence,'' as defined in section 513(a)(3) of the FD&C Act and § 860.7(c)(2) (21 CFR 860.7(c)(2)). (See, *e.g., General Medical Co.* v. *FDA,* 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Association* v. *FDA,* 766 F.2d 592 (D.C. Cir. 1985), cert. denied, 474 U.S. 1062 (1985).)

FDA relies upon ''valid scientific evidence'' in the classification process to determine the level of regulation for devices. To be considered in the reclassification process, the valid scientific evidence upon which the Agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, *e.g.,* the contents of a pending PMA. (See section 520(c) of the FD&C Act (21 U.S.C. 360j(c)).) Section 520(h)(4) of the FD&C Act, added by FDAMA, provides

that FDA may use, for reclassification of a device, certain information in a PMA 6 years after the application has been approved. This can include information from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device but does not include descriptions of methods of manufacture or product composition and other trade secrets.

FDAMA added section 510(m) to the FD&C Act (21 U.S.C. 360(m)). Section 510(m) of the FD&C Act provides that a class II device may be exempted from the premarket notification requirements under section 510(k) of the FD&C Act, if the Agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device.

II. Regulatory History of the Device

On August 28, 1979 (44 FR 50497), FDA published a document proposing to classify stair-climbing wheelchair devices as class III requiring premarket approval. The Physical Medicine Device Classification Panel (Panel) recommended class III because the Panel believed that satisfactory performance of this device had not been demonstrated and, therefore, that it was not possible to establish an adequate performance standard for the device. The Panel said the design of the device was experimental and data to support its safe and effective use was not available. The Panel said the device should, therefore, be subject to premarket approval to assure that manufacturers demonstrate satisfactory performance of the device and thus assure its safety and effectiveness. No comments were received on the proposed rule. On November 23, 1983 (48 FR 53032), FDA published a document classifying stair-climbing wheelchairs as class III devices. On May 11, 1987 (52 FR 17732 at 17741), FDA published a document amending the codified language for stair-climbing wheelchairs to clarify that no effective date had been established for the requirement for premarket approval.

On August 18, 1998 (63 FR 44177), FDA published a document proposing to require the filing of a PMA or a notice of competition of a product development protocol (PDP) for stair-climbing wheelchair devices under section 515(b) of the FD&C Act. FDA received no comments on the document but received one citizen petition requesting a change in the classification of the stair-climbing wheelchair from class III to class II. FDA reviewed the petition and determined that there was not sufficient information to establish special controls to reasonably assure the safety and effectiveness of the device. FDA informed the petitioner in a letter dated May 10, 1999, that if additional information was submitted under section 513(e) of the FD&C Act within 30 days to support the reclassification of the device, FDA would review the information. FDA also stated that if the petitioner did not submit additional information within 30 days to show that sufficient information was available to establish special controls to reasonably assure the safety and effectiveness of the device, FDA would deem the reclassification petition withdrawn. FDA did not receive any new information from the petitioner and deemed the reclassification petition withdrawn. On April 13, 2000 (65 FR 19833), FDA published a document that retained in class III stair-climbing wheelchair devices and that required the filing of PMAs or PDPs on or before July 12, 2000.

On November 20, 2012, a reclassification petition was filed with FDA, requesting FDA to reclassify stair-climbing wheelchairs from class III to class II. In accordance with section 513(e) of the FD&C Act and § 860.130(b)(3), based on new information regarding the device, FDA is now proposing to reclassify the stair-climbing wheelchair device from class III to class II.

III. Device Description

A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position and is intended to climb stairs while the patient remains in the chair. Characteristics of the device enabling this capability may include two endless belt tracks that adjust to the angle of the stairs. This may also include a balancing mechanism to steady the chair as it ascends/descends the staircase.

FDA is proposing in this order to slightly modify the identification language from how it is presently written in § 890.3890(a) (21 CFR 890.3890(a)) for a more accurate description of devices in this classification.

IV. Proposed Reclassification

FDA is proposing that stair-climbing wheelchairs be reclassified from class III to class II. In this proposed order, the Agency has identified special controls under section 513(a)(1)(B) of the FD&C Act that, together with general controls (including prescription use restrictions) applicable to the devices, would provide reasonable assurance of their safety and effectiveness. FDA believes that the identified special controls in this proposed order, if finalized, together with general controls applicable to the device, would provide reasonable assurance of safety and effectiveness. Absent the special controls identified in this proposed order, general controls applicable to the device are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, in accordance with sections 513(e) of the FD&C Act and § 860.130, based on new information with respect to the devices and taking into account the public health benefit of the use of the device and the nature and known incidence of the risk of the device, FDA is proposing to reclassify this preamendments class III device into class II. FDA believes that this new information is sufficient to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for stair-climbing wheelchairs.

Section 510(m) of the FD&C Act authorizes the Agency to exempt class II devices from premarket notification (510(k)) submission. FDA has considered stair-climbing wheelchairs in accordance with the reserved criteria set forth in section 513(a) of the FD&C Act and determined that these devices require premarket notification. Therefore, the Agency does not intend to exempt this proposed class II device from premarket notification (section 510(k) of the FD&C Act) submission as provided for under section 510(m) of the FD&C Act.

V. Risks to Health

After considering the information from the reports and recommendations of the Panel for the classification of these devices, along with information in the petition submitted under section 513(e) of the FD&C Act and any additional information that FDA has at its disposal, FDA has identified and evaluated the risks to health associated with the use of stair-climbing wheelchairs. The petition dated October 22, 2012 (Ref. 1), identified risks to health for all stair-climbing wheelchairs; FDA found these risks to be applicable and identified additional risks to health that apply to stair-climbing wheelchair devices:

- *Instability:* Instability of the device could result in the device tipping over, slipping off an edge (*e.g.,* curb or stair), or sliding down stairs, or use in certain environmental conditions that minimizes frictional coefficient, may result in injury to the user.

• *Entrapment:* The device may entrap a user or a body part if it moves unintentionally, shifts the user into a position from which they are unable to extricate themselves, or pinches a body part against a solid object.

• *Use Error:* A stair-climbing wheelchair may be misused if the user is not properly secured within the seat or if the device is used outside of certain environmental conditions or prescribed step dimensions, structural characteristics.

• *Falls/Fractures:* The device is physically heavy and if the device falls or rolls over a body part of the user or another individual (*e.g.,* caregiver), it can result in serious injury, including fracture.

• *Battery/electrical/mechanical failure:* The device may fail and place the user in an unsafe position (*e.g.,* middle of a street intersection, on stairs). This may result from failure of device critical device components (electronics, battery, brakes) or the device changing operational modes unexpectedly.

• *Pressure sores:* Pressure sores or bruising may result from the user experiencing jarring forces when transitioning over different surfaces or from colliding with solid objects.

• *Burns:* As a result of battery overheating, electrical failure, or ignition of flammable materials, the user may sustain burns.

• *Electric shock:* The user may experience electric shock as a result of battery or electrical failure.

• *Electromagnetic interference:* The device may interfere with the operation of other electrical devices or be susceptible to interference from other electrical devices.

VI. Summary of Reasons for Reclassification

If properly manufactured and used, FDA believes that these devices can be utilized to provide mobility over a variety of terrains and obstacles encountered in everyday life, specifically climbing stairs. Many of these environments would not be accessible and many tasks could not be completed without the availability of a stair-climbing wheelchair. FDA believes that stair-climbing wheelchairs should be reclassified from class III to class II because special controls, in addition to general controls, can be established to provide reasonable assurance of the safety and effectiveness of the devices, and because general controls themselves are insufficient to provide reasonable assurance of its safety and effectiveness. In addition, there is now adequate information sufficient to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification Is Based

FDA believes that the identified special controls, in addition to general controls, are necessary to provide reasonable assurance of safety and effectiveness of these devices. Therefore, in accordance with section 513(e) of the FD&C Act and § 860.130, based on new information with respect to the device, FDA, in response to the petition dated October 22, 2012, and submitted under section 513(e), is proposing to reclassify this preamendments class III device into class II. Since the time of the original panel recommendation and device classification, sufficient evidence has been developed to support a reclassification of stair-climbing wheelchairs from class III to class II with special controls. The petitioner cites the petitioner's own history of use, the petitioner's own preclinical testing, and the development of relevant consensus standards that provide sufficient evidence that stair-climbing wheelchairs can be effective for providing mobility over a variety of terrains and obstacles that are encountered in everyday life. Specifically, the petitioner notes that these devices need to comply with the following consensus standards:

• ''American National Standards Institute (ANSI)/Rehabilitative Engineering & Assistive Technology Society (RESNA) American National Standard for Wheelchairs—Volume 1: Requirements and Test Methods for Wheelchairs (including Scooters),'' sections 1, 5, 7, 8, 11, 13, 15, 16, 22, and 26. These are consensus standards applicable to both powered and mechanical wheelchairs to ensure proper performance regarding static stability, endurance/fatigue testing, and flammability as well as characterization of measurements and dimensions.

• ''ANSI/RESNA American National Standard for Wheelchairs—Volume 2: Additional Requirements for Wheelchairs (including Scooters) with Electrical Systems,'' sections 2, 3, 4, 6, 9, 10, 14, and 21. These are consensus standards applicable to powered wheelchairs to ensure proper performance regarding dynamic stability, brake effectiveness, curb climbing ability, electrical safety testing and electromagnetic compatibility testing as well as characterization of speed/acceleration, battery longevity, and environmental testing.

• ''International Standards Organization (ISO) 7176 Wheelchairs,'' parts 1 to 6, 9 to 11, 13 to 16, and 21. These consensus standards address the same testing and attributes noted in the previously noted volumes of the ANSI/RESNA standards.

FDA believes that this information constitutes sufficient evidence to demonstrate that the proposed special controls can effectively mitigate the risks to health identified in section V of this document, and that these special controls in addition to the general controls will provide a reasonable assurance of safety and effectiveness for stair-climbing wheelchairs.

VIII. Proposed Special Controls

FDA believes that the following special controls, together with general controls (including applicable prescription-use restrictions), are sufficient to mitigate the risks to health described in section V of this document:

• The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

• Performance testing must demonstrate adequate mechanical performance under simulated use conditions and environments. Performance testing must include the following:

○ Fatigue testing;

○ Endurance testing;

○ Resistance to dynamic loads (impact testing);

○ Effective use of the braking mechanism and how the device stops in case of an electrical brake failure;

○ Demonstration of adequate stability of the device on inclined planes (forward, backward, and lateral);

○ Demonstration of the ability of the device to safely ascend and descend obstacles (*e.g.,* stairs, curb); and

○ Demonstration of ability to effectively use the device during adverse temperatures and following storage in adverse temperatures and humidity conditions.

• The skin-contacting components of the device must be demonstrated to be biocompatible.

• Software design, verification, and validation must demonstrate that the device controls, alarms, and user interfaces function as intended.

• Appropriate analysis and performance testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.

• Performance testing must demonstrate battery safety and evaluate longevity.

• Performance testing must evaluate the flammability of device components.

• Patient labeling must bear all information required for the safe and

effective use of the device, specifically including the following:

○ A clear description of the technological features of the device and the principles of how the device works;

○ A clear description of the appropriate use environments/conditions, including prohibited environments;

○ Preventive maintenance recommendations;

○ Operating specifications for proper use of the device such as patient weight limitations, device width, and clearance for maneuverability; and

○ A detailed summary of the device-related adverse events and how to report any complications.

• Clinician labeling must include all the information in the patient labeling noted previously but must also include the following:

○ Identification of patients who can effectively operate the device; and

○ Instructions how to fit, modify, or calibrate the device.

• Usability studies of the device must demonstrate that the device can be used by the patient in the intended use environment with the instructions for use and user training.

Stair-climbing wheelchairs are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device. (Proposed § 890.3890(a) (21 CFR 870.3890(a)); see section 520(e) of the FD&C Act and 21 CFR 801.109 (Prescription devices)). Prescription-use requirements are a type of general control authorized under section 520(e) of the FD&C Act and defined as a general control in section 513(a)(1)(A)(i) of the FD&C Act; and under § 807.81, the device would continue to be subject to 510(k) notification requirements.

IX. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

X. Paperwork Reduction Act of 1995

This proposed order refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

XI. References

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov*.

1. Petition from Deka Research & Development Corp., October 22, 2013 (Docket No. FDA–2012–P–1155).

XII. Proposed Effective Date

FDA is proposing that any final order based on this proposed order become effective on the date of its publication in the **Federal Register** or at a later date if stated in the final order.

XIII. Comments

Interested persons may submit either electronic comments regarding this document or the associated petition to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov*.

XIV. Codification of Orders

Prior to the amendments by FDASIA, section 513(e) provided for FDA to issue regulations to reclassify devices. Although section 513(e) as amended requires FDA to issue final orders rather than regulations, FDASIA also provides for FDA to revoke previously issued regulations by order. FDA will continue to codify classifications and reclassifications in the Code of Federal Regulations (CFR). Changes resulting from final orders will appear in the CFR as changes to codified classification determinations or as newly codified orders. Therefore, under section 513(e)(1)(A)(i), as amended by FDASIA, in this proposed order, we are proposing to revoke the requirements in § 890.3890 related to the classification of stair-climbing wheelchairs as class III devices and to codify the reclassification of stair-climbing wheelchairs into class II.

List of Subjects in 21 CFR Part 890

Medical devices, Physical medicine devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 890 be amended as follows:

PART 890—PHYSICAL MEDICINE DEVICES

■ 1. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 890.3890 is revised to read as follows:

§ 890.3890 Stair-climbing wheelchair.

(a) *Identification.* A stair-climbing wheelchair is a device with wheels that is intended for medical purposes to provide mobility to persons restricted to a sitting position and is intended to climb stairs while the patient remains in the chair. Characteristics of the device enabling this capability may include two endless belt tracks that adjust to the angle of the stairs. This may also include a balancing mechanism to steady the chair as it ascends/descends the staircase.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.

(2) Performance testing must demonstrate adequate mechanical performance under simulated use conditions and environments. Performance testing must include the following:

(i) Fatigue testing;

(ii) Endurance testing;

(iii) Resistance to dynamic loads (impact testing);

(iv) Effective use of the braking mechanism and how the device stops in case of an electrical brake failure;

(v) Demonstration of adequate stability of the device on inclined planes (forward, backward and lateral);

(vi) Demonstration of the ability of the device to safely ascend and descend obstacles (*e.g.,* stairs, curb); and

(vii) Demonstration of ability to effectively use the device during adverse temperatures and following storage in adverse temperatures and humidity conditions.

(3) The skin-contacting components of the device must be demonstrated to be biocompatible.

(4) Software design, verification, and validation must demonstrate that the device controls, alarms, and user interfaces function as intended.

(5) Appropriate analysis and performance testing must be conducted to verify electrical safety and electromagnetic compatibility of the device.

(6) Performance testing must demonstrate battery safety and evaluate longevity.

(7) Performance testing must evaluate the flammability of device components.

(8) Patient labeling must bear all information required for the safe and effective use of the device, specifically including the following:

(i) A clear description of the technological features of the device and the principles of how the device works;

(ii) A clear description of the appropriate use environments/conditions, including prohibited environments;

(iii) Preventive maintenance recommendations;

(iv) Operating specifications for proper use of the device such as patient weight limitations, device width, and clearance for maneuverability; and

(v) A detailed summary of the device-related adverse events and how to report any complications.

(9) Clinician labeling must include all the information noted previously in the patient labeling but must also include the following:

(i) Identification of patients who can effectively operate the device; and

(ii) Instructions how to fit, modify, or calibrate the device.

(10) Usability studies of the device must demonstrate that the device can be used by the patient in the intended use environment with the instructions for use and user training.

Dated: June 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13864 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 1000

[Docket No. FR–5650–N–03]

Indian Housing Block Grant Allocation Formula: Notice of Proposed Negotiated Rulemaking Committee Membership

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of proposed negotiated rulemaking committee membership.

SUMMARY: On September 18, 2012, HUD published a document in the **Federal Register** requesting nominations for membership on the negotiated rulemaking committee that will develop regulatory changes to the funding formula for the Indian Housing Block Grant program authorized by the Native American Housing Assistance and Self-Determination Act of 1996 (NAHASDA). In accordance with section 564 of the Negotiated Rulemaking Act, this document establishes the committee, announces the names and affiliations of the committee's proposed members, requests public comment on the committee and its proposed membership, explains how additional nominations for committee membership may be submitted, and provides other information regarding the negotiated rulemaking process.

DATES: *Comment Due Date:* July 12, 2013.

ADDRESSES: Interested persons are invited to submit comments regarding this notice to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500. Communications must refer to the above docket number and title. There are two methods for submitting public comments. All submissions must refer to the above docket number and title.

1. *Submission of Comments by Mail.* Comments may be submitted by mail to the Regulations Division, Office of General Counsel, Department of Housing and Urban Development, 451 7th Street SW., Room 10276, Washington, DC 20410–0500.

2. *Electronic Submission of Comments.* Interested persons may submit comments electronically through the Federal eRulemaking Portal at *www.regulations.gov.* HUD strongly encourages commenters to submit comments electronically. Electronic submission of comments allows the commenter maximum time to prepare and submit a comment, ensures timely receipt by HUD, and enables HUD to make them immediately available to the public. Comments submitted electronically through the *www.regulations.gov* Web site can be viewed by other commenters and interested members of the public. Commenters should follow the instructions provided on that site to submit comments electronically.

Note: To receive consideration as public comments, comments must be submitted through one of the two methods specified above. Again, all submissions must refer to the docket number and title of the rule.

No Facsimile Comments. Facsimile (fax) comments are not acceptable. Public Inspection of Public Comments. All properly submitted comments and communications submitted to HUD will be available for public inspection and copying between 8 a.m. and 5 p.m. weekdays at the above address. Due to security measures at the HUD Headquarters building, an advance appointment to review the public comments must be scheduled by calling the Regulations Division at 202–708–3055 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number via TTY by calling the Federal Relay Service at 800–877–8339. Copies of all comments submitted are available for inspection and downloading at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Rodger Boyd, Deputy Assistant Secretary for Native American Programs, Room 4126, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, telephone number: 202–401–7914 (this is not a toll-free number). Hearing- or speech-impaired individuals may access this number via TTY by calling the toll-free Federal Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

I. Background

The Native American Housing Assistance and Self-Determination Act of 1996 (25 U.S.C. 4101 *et seq.*) (NAHASDA) changed the way that housing assistance is provided to Native Americans. NAHASDA eliminated several separate assistance programs and replaced them with a single block grant program, known as the Indian Housing Block Grant (IHBG) program. In addition, title VI of NAHASDA authorizes federal guarantees for financing of certain tribal activities (Title VI Loan Guarantee program). The

regulations governing the IHBG and Title VI Loan Guarantee programs are located in part 1000 of HUD's regulations in title 24 of the Code of Federal Regulations. In accordance with section 106 of NAHASDA, HUD developed the regulations with active tribal participation, using the procedures of the Negotiated Rulemaking Act of 1996 (5 U.S.C. 561–570).

Under the IHBG program, HUD makes assistance available to eligible Indian tribes for affordable housing activities. The amount of assistance made available to each Indian tribe is determined using a formula that was developed as part of a prior NAHASDA negotiated rulemaking process. A regulatory description of the allocation formula under the IHBG program is located in Subpart D of 24 CFR part 1000. In general, the amount of funding for a tribe is the sum of the formula's need component and the Formula Current Assisted Stock (FCAS) component, subject to a minimum funding amount authorized under the regulations. Based on the amount of funding appropriated annually for the IHBG program, HUD calculates the annual grant for each Indian tribe, and provides this information to the Indian tribes. An Indian Housing Plan for the Indian tribe is then submitted to HUD. If the Indian Housing Plan is found to be in compliance with statutory and regulatory requirements, the grant is made.

II. The Negotiated Rulemaking Committee

This notice announces the proposed membership of the negotiated rulemaking committee. In making its proposed selections for membership on the negotiated rulemaking committee, HUD's goal was to establish a committee whose membership reflects a balanced representation of Indian tribes. Selections were based on those nominees who met the eligibility criteria for membership contained in the September 18, 2012, **Federal Register** notice (77 FR 57544). HUD is satisfied that the proposed membership reflects a geographically diverse cross-section of small, medium, and large Indian tribes. In addition to the tribal members of the committee, there will be one or more HUD representatives on the negotiated rulemaking committee. After careful consideration of the public comments received on this proposed list of committee members, HUD will announce the final composition of the negotiated rulemaking committee in a subsequent **Federal Register** notice.

HUD proposes to make the following (23) selections for tribal membership on the negotiated rulemaking committee:

Jason Adams, Executive Director, Salish-Kootenai Housing Authority, Pablo, Montana.
Annette Bryan, Executive Director, Puyallup Housing Authority, Tacoma, Washington.
Heather Cloud, Representative, Ho-Chunk Nation, Tomah, Wisconsin.
Gary Cooper, Executive Director, Cherokee Nation, Tahlequah, Oklahoma
Pete Delgado, Executive Director, Tohono O'odham Housing Authority, Sells, Arizona.
Sami Jo Difuntorum, Executive Director, Siletz Tribal Housing Department, Siletz, Oregon.
Jason Dollarhide, Second Chief, Peoria Tribe of Indians, Miami, Oklahoma.
Earl Evans, Councilor, Haliwa-Saponi Tribe, Hollister, North Carolina.
Karin Lee Foster, Legal Counsel, Yakama Housing Authority, Yakima, Washington.
Carol Gore, President/CEO, Cook Inlet Housing Authority, Anchorage, Alaska.
Lafe Haugen, Executive Director, Northern Cheyenne Housing Authority, Lame Deer, Montana.
Richard Hill, General Manager, Mille Lacs Housing Authority, Onamia, Minnesota.
Leon Jacobs, Representative, Lumbee Tribe, Pembroke, North Carolina.
Teri Nutter, Executive Director, Cooper River Basin Regional Housing Authority, Glennallen, Alaska.
Sam Okakok, Housing Director, Barrow, Alaska.
Diana Phair, Executive Director, Lummi Nation, Bellingham, Washington.
Michael Reed, CEO, Cocopah Indian Housing and Development, Somerton, Arizona.
Jack Sawyers, Special Projects, Paiute Tribe of Utah, Cedar City, Utah.
Marty Shuravloff, Executive Director, Kodiak Island Housing Authority, Kodiak, Alaska.
Russell Sossamon, Executive Director, Choctaw Housing Authority, Hugo, Oklahoma.
Michael Thom, Vice Chair, Karuk Tribe, Happy Camp, California.
Sharon Vogel, Executive Director, Cheyenne River Housing Authority, Eagle Butte, South Dakota.
Aneva Yazzie, CEO, Navajo Housing Authority, Window Rock, Arizona.

III. Request for Comments and Committee Nominations

Persons may submit comments on HUD's establishment of the formula negotiating rulemaking committee and may submit additional nominations for committee membership in accordance with the **ADDRESSES** section above. Nominations for membership on the Committee must include:

1. The name of your nominee and a description of the interests the nominee would represent;
2. Evidence that your nominee is authorized to represent a tribal government, which may include the tribally designated housing entity of a tribe, with the interests the nominee would represent, so long as the tribe provides evidence that it authorizes such representation;
3. A written commitment that the nominee will actively participate in good faith in the development of the rule; and
4. The reasons that the persons proposed above do not adequately represent the interests of the person submitting the nomination.

IV. Committee Meetings

At this time, HUD has not finalized the schedule and agenda for the committee meetings. HUD will provide administrative support to the committee. Notice of committee meetings will be published in the **Federal Register**. Meetings of the negotiated rulemaking committee will be open to the public without advance registration. Public attendance may be limited to the space available. Members of the public will be provided with an opportunity to make statements during the meeting, to the extent that time permits, and to file written statements with the committee for its consideration. In the event that the logistics of the committee meetings are changed, HUD will advise the public through **Federal Register** notice.

Dated: June 5, 2013.

Sandra B. Henriquez,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 2013–13984 Filed 6–11–13; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF EDUCATION

34 CFR Chapter VI

[Docket ID ED–2013–OPE–0077]

Negotiated Rulemaking Committee, Negotiator Nominations and Schedule of Committee Meetings—Title IV Federal Student Aid Programs, Gainful Employment in a Recognized Occupation

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Intention to establish negotiated rulemaking committee.

SUMMARY: We announce our intention to establish a negotiated rulemaking committee to prepare proposed regulations for the Federal Student Aid programs authorized under title IV of the Higher Education Act of 1965, as amended (HEA) (title IV Federal Student Aid programs). The proposed regulations would establish standards for programs that prepare students for gainful employment in a recognized occupation. This committee will include representatives of organizations or groups with interests that are significantly affected by the subject matter of the proposed regulations. We request nominations for individual negotiators who represent key stakeholder constituencies for the issue to be negotiated to serve on the committee and we set a schedule for committee meetings.

The Department continues to review and appreciates and values the testimony offered at the public hearings and the comments submitted through the public comment process regarding other proposed rulemaking topics, including: cash management of funds provided under title IV Federal Student Aid programs; regulations designed to prevent fraud; State authorization for programs offered through distance education or correspondence education; State authorization for foreign locations of institutions located in a State; clock to credit hour conversion; changes made by the Violence Against Women Reauthorization Act of 2013 to the campus safety and security reporting requirements in the HEA; the definition of ''adverse credit'' for borrowers in the Federal Direct PLUS Loan Program; and campus-based Federal Student Aid program reforms. We anticipate announcing our intention to establish a negotiated rulemaking committee or committees to consider some or all of these rulemaking issues in the coming months.

DATES: We must receive your nominations for negotiators to serve on the committee on or before July 12, 2013. The dates, times, and locations of the committee meetings are set out in the *Schedule for Negotiations* section under **SUPPLEMENTARY INFORMATION**, below.

ADDRESSES: Please send your nominations for negotiators to Wendy Macias, U.S. Department of Education, 1990 K Street NW., Room 8017, Washington, DC 20006. Telephone: (202) 502–7526 or by email: *wendy.macias@ed.gov*.

FOR FURTHER INFORMATION CONTACT: For information about the content of this notice, including information about the negotiated rulemaking process or the nomination submission process, contact: Wendy Macias, U.S. Department of Education, 1990 K Street NW., room 8017, Washington, DC 20006. Telephone: (202) 502–7526 or by email: *wendy.macias@ed.gov*.

For general information about the negotiated rulemaking process, see *The Negotiated Rulemaking Process for Title IV Regulations, Frequently Asked Questions* at *http://www2.ed.gov/policy/highered/reg/hearulemaking/hea08/neg-reg-faq.html*.

If you use a telecommunications device for the deaf or text telephone, call the Federal Relay Service, toll free, at 1–800–877–8339.

Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

SUPPLEMENTARY INFORMATION: On May 1, 2012, we published a notice in the **Federal Register** (77 FR 25658) announcing our intent to establish a negotiated rulemaking committee under section 492 of the HEA to develop proposed regulations designed to prevent fraud and otherwise ensure proper use of title IV Federal Student Aid program funds, especially within the context of current technologies. In particular, we announced our intent to propose regulations to address the use of debit cards and other banking mechanisms for disbursing title IV Federal Student Aid program funds, and to improve and streamline the campus-based Federal Student Aid programs. We also announced two public hearings at which interested parties could comment on the topics suggested by the Department and suggest additional topics for consideration for action by the negotiated rulemaking committee. Those hearings were held on May 23, 2012, in Phoenix, Arizona, and on May 31, 2012, in Washington, DC. We invited parties to comment and submit topics for consideration in writing as well.

On April 16, 2013, we published a notice in the **Federal Register** (78 FR 2247), as corrected at 78 FR 25235, announcing additional topics for consideration for action by the negotiated rulemaking committee. The additional topics for consideration are: cash management of funds provided under the title IV Federal Student Aid programs; State authorization for programs offered through distance education or correspondence education; State authorization for foreign locations of institutions located in a State; clock to credit hour conversion; gainful employment; changes made by the Violence Against Women Reauthorization Act of 2013, Public Law 113–4, to the campus safety and security reporting requirements in the HEA; and the definition of ''adverse credit'' for borrowers in the Federal Direct PLUS Loan Program. We announced three public hearings at which interested parties could comment on the new topics suggested by the Department and suggest additional topics for consideration for action by the negotiating committee. On May 13, 2013, we announced in the **Federal Register** (78 FR 27880) the addition of a fourth hearing. The hearings were held on May 21, 2013, in Washington, DC; May 23, 2013, in Minneapolis, Minnesota; May 30, 2013, in San Francisco, California; and June 4, 2013, in Atlanta, Georgia. We also invited parties unable to attend a public hearing to submit written comments on the additional topics and to submit other topics for consideration. Transcripts from all six public hearings will be found once they are available at *http://www2.ed.gov/policy/highered/reg/hearulemaking/2012/index.html*. Written comments submitted in response to the May 1, 2012, and April 16, 2013, notices may be viewed through the Federal eRulemaking Portal at *www.regulations.gov*. Instructions for finding comments are available on the site under ''How to Use Regulations.gov'' in the Help section. Individuals can enter docket ID ED–2012–OPE–0008 in the search box to locate the appropriate docket.

Regulatory Issues: After consideration of the information received at the regional hearings and the submitted written comments, we have decided to establish, at this time, one negotiating committee to prepare proposed regulations for the title IV Federal Student Aid programs establishing standards for programs that prepare students for gainful employment in a recognized occupation.

We intend to select negotiators for the committee who represent the interests significantly affected by the establishment of standards for programs that prepare students for gainful employment in a recognized occupation. In so doing, we will follow the requirement in section 492(b)(1) of the HEA that the individuals selected must have demonstrated expertise or experience in the relevant subject under negotiation. We will also select

individual negotiators who reflect the diversity among program participants, in accordance with section 492(b)(1) of the HEA. Our goal is to establish a committee that will allow significantly affected parties to be represented while keeping the committee size manageable.

The committee may create subgroups on particular aspects of this topic that may involve additional individuals who are not members of the committee. Such individuals who are not selected as members of the committee will be able to attend the meetings, have access to the individuals representing their constituencies, and participate in informal working groups on various issues between the meetings. The committee meetings will be open to the public.

Through the publication of future **Federal Register** notices in the coming months, we intend to establish committees to address other rulemaking issues.

Constituencies: We have identified the following constituencies as having interests that are significantly affected by the topic proposed for negotiations. The Department plans to seat as negotiators individuals from organizations or groups representing these constituencies:

- Students.
- Legal assistance organizations that represent students.
- Consumer advocacy organizations.
- Financial aid administrators at postsecondary institutions.
- State higher education executive officers.
- State attorneys general and other appropriate State officials.
- Business and industry.
- Institutions of higher education eligible to receive Federal assistance under title III, Parts A, B, and F and title V of the HEA, which include Historically Black Colleges and Universities, Hispanic-Serving Institutions, American Indian Tribally Controlled Colleges and Universities, Alaska Native and Native Hawaiian-Serving Institutions, Predominantly Black Institutions, and other institutions with a substantial enrollment of needy students as defined in title III of the HEA.
- Two-year public institutions of higher education.
- Four-year public institutions of higher education.
- Private, non-profit institutions of higher education.
- Private, for-profit institutions of higher education.
- Regional accrediting agencies.
- National accrediting agencies.
- Specialized accrediting agencies.

The goal of the committee is to develop proposed regulations that reflect a final consensus of the committee. Consensus means that there is no dissent by any member of the negotiating committee, including the committee member representing the Department. An individual selected as a negotiator will be expected to represent the interests of his or her organization or group, and participate in the negotiations in a manner consistent with the goal of developing proposed regulations on which the committee will reach consensus. If consensus is reached, all members of the organization or group represented by a negotiator are bound by the consensus and are prohibited from commenting negatively on the resulting proposed regulations. The Department will not consider any such negative comments that are submitted by members of such an organization or group.

Nominations: Nominations should include:

- The name of the nominee, the organization or group the nominee represents, and a description of the interests that the nominee represents.
- Evidence of the nominee's expertise or experience in the subject to be negotiated.
- Evidence of support from individuals or groups within the constituency that the nominee will represent.
- The nominee's commitment that he or she will actively participate in good faith in the development of the proposed regulations.
- The nominee's contact information, including address, phone number, fax number, and email address.

For a better understanding of the negotiated rulemaking process, nominees should review *The Negotiated Rulemaking Process for Title IV Regulations, Frequently Asked Questions* at *http://www.ed.gov/policy/highered/reg/hearulemaking/hea08/neg-reg-faq.html* prior to committing to serve as a negotiator.

Nominees will be notified whether or not they have been selected as negotiators as soon as the Department's review process is completed.

Schedule for Negotiations: The committee will meet for two sessions on the following dates:

Session 1: September 9–11, 2013.

Session 2: October 21–23, 2013.

Sessions will run from 9:00 a.m. to 5:00 p.m. on the first two days, and 9:00 a.m. to 12:00 p.m. on the last day.

The meetings will be held at the U.S. Department of Education at: 1990 K Street NW., Eighth Floor Conference Center, Washington, DC 20006.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of the Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Program Authority: 20 U.S.C. 1098a.

Dated: June 7, 2013.

Martha Kanter,

Under Secretary for Education.

[FR Doc. 2013–13975 Filed 6–11–13; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2013–0395; FRL–9823–5]

Approval and Promulgation of Air Quality Implementation Plans; Utah; Revisions to Utah Administrative Code—Permit: New and Modified Sources

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to partially approve and partially disapprove State Implementation Plan (SIP) revisions submitted by the State of Utah on September 15, 2006. The September 15, 2006 revisions contain new, amended and renumbered rules in Utah Administrative Code (UAC) Title R–307 that pertain to the issuance of Utah air quality permits. The September 15, 2006 revisions supersedes, in its entirety, and replaces an October 9, 1998 submittal that initially revised provisions in Utah's air quality permit program. In this action, we are proposing to approve all but four of the SIP revisions in the September 15, 2006 submittal. We are proposing to disapprove the State's rules, R307–401–7 (Public Notice), R307–401–9(b) and portions of (c) (Small Source Exemption), R307–401–

12 (Reduction in Air Contaminants), and R307–410–5 (Documentation of Ambient Air Impacts for Hazardous Air Pollutants). We are also proposing to partially approve and partially disapprove R307–410–6 (Stack Heights and Dispersion Techniques). This action is being taken under section 110 of the CAA.

DATES: Comments must be received on or before July 12, 2013.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2013–0395, by one of the following methods:

- *www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Email: leone.kevin@epa.gov*
- *Fax:* (303) 312–6064 (please alert the individual listed in the **FOR FURTHER INFORMATION CONTACT** if you are faxing comments).
- *Mail:* Carl Daly, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129.
- *Hand Delivery:* Carl Daly, Director, Air Program, Environmental Protection Agency (EPA), Region 8, Mailcode 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. Such deliveries are only accepted Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding federal holidays. Special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R08–OAR–2013–0395. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through *www.regulations.gov* or email. The *www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA, without going through *www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the EPA Docket Center homepage at *http://www.epa.gov/epahome/dockets.htm.* For additional instructions on submitting comments, go to section I. General Information of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly-available docket materials are available either electronically in *www.regulations.gov* or in hard copy at the Air Program, Environmental Protection Agency (EPA), Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129. EPA requests that if at all possible, you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. You may view the hard copy of the docket Monday through Friday, 8:00 a.m. to 4:00 p.m., excluding federal holidays.

FOR FURTHER INFORMATION CONTACT: Kevin Leone, Air Program, Mailcode 8P–AR, Environmental Protection Agency, Region 8, 1595 Wynkoop Street, Denver, Colorado 80202–1129, (303) 312–6227, or *leone.kevin@epa.gov.*

SUPPLEMENTARY INFORMATION:

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Definitions

For the purpose of this document, we are giving meaning to certain words or initials as follows:

(i) The words or initials *Act* or *CAA* mean or refer to the Clean Air Act, unless the context indicates otherwise.

(ii) The words *EPA, we, us* or *our* mean or refer to the United States Environmental Protection Agency.

(iii) The initials *SIP* mean or refer to State Implementation Plan.

(iv) The words *State* or *Utah* mean the State of Utah, unless the context indicates otherwise.

(v) The initials *NSR* mean or refer to New Source Review.

(vi) The initials *SIP* mean or refer to State Implementation Plan.

(vii) The initials *UAC* mean or refer to the Utah Administrative Code.

I. General Information

A. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through *www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for Preparing Your Comments.* When submitting comments, remember to:

a. Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** date and page number).

b. Follow directions—The agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

c. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

d. Describe any assumptions and provide any technical information and/or data that you used.

e. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

f. Provide specific examples to illustrate your concerns, and suggest alternatives.

g. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

h. Make sure to submit your comments by the comment period deadline identified.

II. Background

Several revisions to Utah's minor source permitting program were originally submitted to EPA on October 9, 1998. The SIP revisions covered the following three areas of the State's rules: (1) R307–1–1 (Forward and Definitions); (2) R307–1–3 (Control of Installations); and R307–15–6(5) (Permit Content).[1] On September 20, 1999, Utah submitted a revision that renumbered the regulatory provisions in the October 9, 1998 submittal. On September 15, 2006, Utah submitted additional revisions to the minor source permitting program and some of the rules were renumbered a second time.

A cross-walk table comparing the provisions from the October 9, 1998, September 20, 1999, and September 15, 2006 submittals is included in the docket for this action. The September 15, 2006 submittal supersedes and replaces the October 9, 1998 submittal in its entirety and partially supersedes and replaces the September 20, 1999 submittal, as outlined in the cross-walk table. As explained below, we approved a subsequent revision of the regulations contained in Definitions Section, and therefore we are not taking action on R307–1–1 in this action. See 73 FR 51222 (September 2, 2008).

Utah's September 15, 2006, submittal covers four groups of rules: (1) Revised R307–101–2 (Definitions), which we previously acted on in 73 FR 51222; (2) added a new section R307–401 (Notice of Intent and Approval Order);[2] (3) added a new section R307–410 (Permits: Emission Impact Analysis);[3] and (4) renumbered rules in State rule section R307–413 (Permit: Exemptions and Special Provisions) to R307–401. The permit exemptions in Utah's October 9, 1998, submittal (R307–1–3.1.7) were renumbered by the State to R307–413 in Utah's September 20, 1999, submittal. In the September 15, 2006 submittal, some of the rules which were renumbered to R307–413 were then renumbered a second time by the State to R307–401.

The purpose of the State's SIP actions in the September 15, 2006 submittal was to separate minor source permitting and modeling requirements in Title R307 from major source permitting and modeling requirements in Title R307. The September 15, 2006, submittal supersedes and replaces Utah's October 9, 1998, submittal; thus, by acting on the September 15, 2006, submittal we are also concurrently acting on the October 9, 1998 submittal.

III. What action is EPA taking?

The rules outlined below represent the rules submitted by Utah on September 15, 2006. These rules supersede and replace corresponding citations from Utah's September 20, 1999 and October 9, 1998 submittals (See Table 1—Rulemaking Crosswalk in docket).

R307–101–2 (Definitions)

In Utah's October 9, 1998 submittal, the State requested the addition of the definitions ''Air Quality Related Values'' and ''Carcinogen'' in R307–1–1 (Forward and Definitions) to the SIP. In Utah's September 20, 1999 submittal, R307–1–1 was renumbered to R307–101–2. The September 15, 2006, submittal requested the deletion of two definitions in R307–101–2 (''Air Quality Related Values'' and ''Significant''. In 73 FR 51222 (September 2, 2008), EPA incorporated by reference UAC R307–101–2 as adopted by the Utah Air Quality Board on February 6, 2008, effective on February 8, 2008. Therefore, our 73 FR 51222 action superseded and replaced R307–1–1, as submitted on October 9, 1998, and R307–101–2, as submitted on September 15, 2006. We approved the 2008 version of the rule into Utah's SIP on September 2, 2008 and incorporated it by reference into the Code of Federal Regulations. See 73 FR 51222.'' Thus, in this proposal, we do not need to act on the September 15, 2006 version of R307–101–2. (see Table 1—Rulemaking cross-walk in docket).

R307–401 (Permit: Notice of Intent and Approval Order)

We are proposing to approve new rule R307–401–1 (Purpose). This rule explains that the R307–401 rules establish the application and permit requirements for new and modified sources. R307–401–1 states there are additional permitting requirements for larger sources or sources located in nonattainment or maintenance areas. The rule also states the exemptions listed in R307–401 do not affect the applicability of other permitting rules in the SIP.

We are proposing to approve R307–401–2 (Definitions). We are proposing to approve these definitions because they are consistent with applicable federal rules, as described in Table 2—Definitions Cross-walk. Additionally, the definitions have either been renumbered from prior State rules or contain approvable changes to the definition. (see Table 2—Definitions Crosswalk in docket).

We are proposing to approve R307–401–3 (Applicability). This rule outlines: (1) what type of activities are applicable to the requirements in R307–401; (2) other sections in R307 which may establish additional permitting requirements; (3) how exemptions in R307–401 affect applicability of other requirements in R307; and (4) how exemptions in other sections in R307 affect applicability of requirements in R307–401. R307–401–3 (2)(a) and (b) contains specific safeguards that clarify that sources may also have additional permitting requirements in other permitting rules in the SIP. This rule is particularly significant because it clarifies that sources which are exempt in sections R307–401–9 through R307–401–17 cannot circumvent major NSR requirements.

We are proposing to approve R307–401–4 (General Requirements). R307–401–4 applies to all new and modified sources, including sources that are exempt from the requirements to obtain an approval order. This rule requires: (1) control apparatus installed at the source shall be adequately and properly maintained; (2) under certain circumstances, the executive secretary may require an exempted source to submit a notice of intent and obtain an approval order in accordance with R307–401–5 through R307–401–8; and (3) with certain exceptions, fuel combustion devices shall be replaced with low oxide of nitrogen burners. We are proposing to approve R307–401–4(1) and (3) because they comply with 40 CFR 51.160(a) and (b). Additionally, R307–401–4(2) complies with 40 CFR 51.160(b) because it provides a means by which the State or local agency can prevent an otherwise exempted source from violating applicable portions of the control strategy or interfering with attainment or maintenance of the National Ambient Air Quality Standards (NAAQS).

We are proposing to approve R307–401–5 (Notice of Intent). The requirements in R307–401–5 contain a list of information that shall be included with a notice of intent submitted by any person to the State. The rule clarifies that the notice of intent requirements do not apply to R307–401–9 through R307–

[1] While the SIP submittal contains numerous rules, the three-page Enclosure to the Governor's cover letter identifies these three specific rule amendments that were submitted to EPA for review and approval.

[2] The regulations impacted in the submittal from the Notice of Intent and Approval Order section include the following: R307–401–1, R307–401–2, R307–401–3, R307–401–4, R307–401–5, R307–401–6, R307–401–7, R307–401–8, R307–401–9, R307–401–10, R307–401–11, R307–401–12, R307–401–13, R307–401–14, R307–401–15, R307–401–16, R307–401–17, R307–401–18, R307–401–19, and R307–401–20.

[3] The regulations impacted in the submittal from the Permits: Emission Impact Analysis section include the following: R307–410–1, R307–410–2, R307–410–3, R307–410–4, R307–410–5, and R307–410–6.

401–17. The notice of Intent requirements outlined in R307–401–5(1) and (2)(a)–(k) meet the requirements of 40 CFR 51. 160(a), (c) and (e) because (1) the procedures allow the State or a local agency to determine whether the project will result in a violation of applicable portions of the control strategy or interfere with attainment or maintenance of the NAAQS; (2) the procedures provide for the submission to include: information on the nature and amounts of emissions to be emitted; the location, design, construction and operation of the facility, building, structure, or installation necessary for the State or a local agency to make a determination whether the project will result in a violation of applicable portions of the control strategy or interfere with attainment or maintenance of the NAAQS; and (3) the procedures provide that the owner must identify the types and sizes of facilities, buildings, structures, or installations which will be subject to review.

We are proposing to approve R307–401–6 (Review Period). R307–401–6 contains the deadlines and procedures applicable to the State in processing a notice of intent. R307–401–6(2)(b) meets the requirement of 40 CFR 51.160(a) because the rule provides the State or a local agency the opportunity to determine whether the project will result in a violation of applicable portions of the control strategy or interfere with attainment or maintenance of the NAAQS. R307–401–6(2)(b) also meets the requirement of 40 CFR 51. 160(b), because the rule provides a means for the State or a local agency can prevent an exempted source from violating applicable portions of the control strategy or interfering with attainment or maintenance of the NAAQS.

We are proposing to disapprove R307–401–7 (Public Notice). R307–401–7 revised Utah's public notice procedures to allow for a 10-day public comment period for an approval or disapproval order issued under R307–401–8. The rule allows for the public comment period to be increased to 30 days under certain conditions. We note that the public comment period for an approval or disapproval order currently in Utah's federally approved SIP is 30 days. (See R307–1–3.1.3) Federal regulations for Public Availability of Information found at 40 CFR 51.161(b)(2) require at a minimum a 30-day public comment period for the permitting of a source, including minor source permits. In addition, the 30-day comment period is important to allow adequate opportunity for comment by other affected states, federal agencies, and the public.

We are proposing to approve R307–401–8 (Approval Order). This rule describes the conditions that must be met before the State will issue and approval order. R307–401–8 is consistent with the Federal requirements located in 40 CFR 51.160(a) because the rule provides the State or a local agency the opportunity to determine whether the project will result in a violation of applicable portions of the control strategy or interfere with attainment or maintenance of the NAAQS. The rule is also consistent with 40 CFR 51.160(b) because the rule provides a means for the State or a local agency can prevent an otherwise exempted source from violating applicable portions of the control strategy or interfering with attainment or maintenance of the NAAQS. In addition, R307–401–8 lists additional safeguards to clarify that sources may also have additional permitting requirements in other State regulations. R307–401–8(b)(i) and (ii) is particularly significant because they prohibit sources from circumventing major NSR requirements.

We are proposing to partially approve and partially disapprove R307–401–9 (Small Source Exemptions). R307–401–9 creates a *de minimis* exemption threshold from the requirement to submit a notice of intent and apply for an approval order prior to initiation of construction, modification, or relocation. There currently is no *de minimis* exemption threshold from notice of intent and approval order requirements approved into the Utah SIP. Section 110(l) of the CAA states that EPA cannot approve a SIP revision that would interfere with any applicable requirement concerning attainment or reasonable further progress (RFP), as defined in section 171 of the CAA, or any other applicable requirement of the CAA. The State submitted a CAA 110(l) demonstration of noninterference (see docket).

R307–401–9 provides that a stationary source is exempt from the requirement to obtain an approval order in R307–401–5 through 8 if the following conditions are met: (1) Actual emissions are less than five tons per year of any criteria pollutant; (2) actual emissions are less than 500 pounds per year of any hazardous air pollutant (HAP) or less than 2000 pounds per year of any combination of HAPs; and (3) actual emissions are less than 500 pounds per year of air contaminant not included above and are less than 2000 pounds per year of any combination of air contaminant not included in above.

We are proposing to approve all of R307–401–9, except for paragraph (b) and the portions of paragraph (c) that reference paragraph (b). We are proposing to disapprove R307–401–9(b) and the phrase ''or (b)'' in paragraph (c) because EPA lacks authority in an action on a SIP revision under CAA section 110 to approve provisions addressing hazardous air pollutants. Thus we are proposing to disapprove these specific provisions. We are proposing to approve all of R307–401–9, except for paragraph (b) and the portions of paragraph (c) that reference paragraph (b) because:

R307–401–9 contains a safeguard that a source shall no longer be exempt and is required to submit a notice of intent if its actual emissions exceed the thresholds listed in R307–401–9(1)(a). In addition, sources receiving an exemption under R307–401–9 are still subject to the requirements located in: (1) R307–401(2)(a), which prevents exempt sources from circumventing major NSR requirements; (2) R307–401–4, which contains the general permitting requirements; (3) State permitting area source regulations under R307–201 through 207; and (4) R307 section 300 that contains the State permitting nonattainment and maintenance area regulations (see docket, 110(l) demonstration of noninterference). The exemption thresholds and the additional safeguards just described ensure NAAQS protection and thus meet the requirements of CAA 110(a)(2)(C) and 40 CFR 51.160.

EPA's regulations at 40 CFR 51.160 do not require the issuance of a permit for the construction or modification of minor sources, but only that the SIP include a procedure to prevent the construction of a source or modification that would violate the SIP control strategy or interfere with attainment or maintenance of the NAAQS.

EPA recognizes that, under the applicable federal regulations, states have broad discretion to determine the scope of their minor NSR programs as needed to attain and maintain the NAAQS. A state may tailor its minor NSR requirements as long as they are consistent with the requirements of CAA 110(a)(2)(C) and 40 CFR part 51.160—164. States may also provide a rationale for why the rules are at least as stringent as the 40 CFR part 51 requirements where the revisions are different from those in 40 CFR part 51.

The State has shown through their CAA 110(l) demonstration that while sources below the *de minimis* exemption permit thresholds in R307–401–9 are no longer required to undergo a case-by-case review and receive an

approval order, they are still regulated by other rules within R307–401 and underlying statewide area source rules in Title R307.

In addition, the *de minimis* level permit threshold in R307–401–9, which has been implemented as a state-approved rule since 1996, is comparable to the *de minimis* level threshold in many of the federally enforceable minor NSR programs in surrounding states such as Idaho, Montana, and North Dakota, and for sources covered by EPA's tribal NSR rule for sources located in Indian Country.

EPA notes that we have approved several similar *de minimis* exemption provisions in other states as follows:

a. On January 16, 2003, EPA approved a minor NSR program for the State of Idaho (68 FR 2217). This rule allows changes to be considered exempt from permitting if the source's uncontrolled potential emissions are less than ten percent (10%) of the NSR significant emissions rate. For example: 1.5 tons per year for PM_{10}, 4 tons per year for volatile organic compounds (VOCs), nitrogen dioxide (NO_2), and sulfur dioxide (SO_2), and 10 tons per year for carbon monoxide (CO). EPA determined in this instance that states may exempt from minor NSR certain categories of changes based on *de minimis* or administrative necessity grounds in accordance with the criteria set out in *Alabama Power Co.* v. *Costle,* 636 F.2d 323 (D.C. Cir. 1979). *De minimis* sources are presumed to not have an impact and the state has determined that their emissions would not prevent or interfere with attainment of the NAAQS, even within nonattainment areas.

b. On February 13, 2012, EPA approved a five tons per year potential emissions level as a *de minimis* threshold to be exempt from permitting requirements in the State of Montana (77 FR 7531). In this final rulemaking, EPA determined this *de minimis* threshold met the requirements of CAA section 110(a)(2)(C), 40 CFR part 51.160 and CAA section 110(l).

c. On July 1, 2011, EPA finalized the tribal NSR rule (76 FR 38748). In this rulemaking, EPA established *de minimis* thresholds at which sources are to be exempt from permitting requirements for each regulated NSR pollutant (see 40 CFR 49.153—Table 1) utilizing an allowable-to-allowable applicability test. EPA stated in this rulemaking that these threshold levels represent a reasonable balance between environmental protection and economic growth (76 FR 38758). EPA further recognized in designing the tribal NSR rule, that the overarching requirement is ensuring NAAQS protection (76 FR 38756) as described in CAA section 110(a)(2)(C). In order to determine that the sources below minor NSR permit thresholds in 40 CFR 49.153—Table 1 would be inconsequential to attainment or maintenance of the NAAQS, EPA performed a national source distribution analysis (see 71 FR 48702). In this analysis, EPA looked at size distribution of existing sources across the country. Using the National Emissions Inventory (NEI), which includes the most comprehensive inventory of existing U.S. stationary point sources that is available, EPA determined how many of these sources fall below the proposed minor NSR thresholds (see 71 FR 48702, Table 2). For each pollutant, EPA found that only around 1 percent (or less) of total emissions would be exempt from review under the minor NSR program. At the same time, the thresholds would promote an effective balance between environmental protection and source burden because anywhere from 42 percent to 76 percent of sources (depending on the pollutant) would be too small to be subject to preconstruction review (76 FR 38758). Utah, which contains areas of Indian country that are subject to the permitting thresholds in the tribal NSR rule, has established generally lower exemption levels than those in the tribal NSR rule. In addition, as EPA explained in the tribal NSR rule, this will ''allow us to begin leveling the playing field with the surrounding state programs and will result in a more cost-effective program by reducing the burden on sources and reviewing authorities.'' (see 76 FR 38758).

d. On May 27, 2008, EPA approved a 25 tons per year actual emissions level as a *de minimis* threshold for fossil fuel burning equipment to be exempt from permitting requirements in the State of North Dakota, and a 5 ton per year actual emissions level as a *de minimis* threshold for any internal combustion engine, or multiple engines to be exempt from permitting requirements (73 FR 30308). EPA determined the revision will not adversely impact the NAAQS or PSD increments (73 FR 30308).

e. On February 1, 2006, EPA approved a 5 tons per year actual emissions level as a *de minimis* threshold to be exempt from permitting requirements in the State of North Carolina (see 61 FR 3584).

We are proposing to approve R307–401–9 because: (1) R307–401–9 has safeguards which prevent circumvention of NSR requirements; (2) the State's 110(l) demonstration shows sources are still regulated by other rules within R307–401 and underlying statewide area source rules in Title R307; (3) R307–401–9 is similar to the *de minimis* level threshold in many of the federally enforceable minor NSR programs in surrounding states and around the country; and (4) Utah, which contains areas of Indian country that are subject to the permitting thresholds in the tribal NSR rule, has established generally lower exemption levels than those in the tribal NSR rule.

We are proposing to approve R307–401–10 (Source Category Exemptions). R307–401–10, as submitted on September 20, 1999, was originally titled ''Low Oxides of Nitrogen Burner Technology''. In Utah's September 15, 2006 submittal, this was deleted and moved to R307–325; R307–401–10 was then replaced with ''Source Category Exemptions'' (see Table 1—Rulemaking Crosswalk).

Sources receiving an exemption under R307–401–10 are still subject to the requirements located in: (1) R307–401(2)(a), which prevents exempt sources from circumventing major NSR requirements; (2) R307–401–4, which contains the general permitting requirements; (3) R307–201 through 207, which contains the State permitting area source regulations; and (4) R307 section 300, which contains the State permitting nonattainment and maintenance area regulations (see docket, 110(l) demonstration of noninterference). The exemption thresholds and the additional regulatory safeguards just described ensure NAAQS protection and thus meet the requirements of 110(a)(2)(C) and 40 CFR 51.160.

We are proposing to approve R307–401–11 (Replacement-in-Kind Equipment). This rule applies to existing process equipment or pollution control equipment covered by an existing approval order or SIP requirement. Before equipment may be replaced using the procedures in this rule and in lieu of filing a notice of intent, R307–401–11(2)(a) requires the owner or operator of a stationary source to submit written notification to the executive secretary. This notification contains a description of the replacement-in-kind equipment including the control capability of any control apparatus and demonstrations that the conditions in R307–401–11(1) are met. One of these conditions is R307–401–11(1)(h), which requires the source to demonstrate that the replacement of the control apparatus or process equipment does not violate any provisions of Title R307, including: R307–403 (New and Modified Sources in Nonattainment and Maintenance Areas) and R307–405 (PSD). This is further clarified in R307–401–3(2)(a),

which states, ''Exemptions contained in R307–401 do not affect applicability or other requirements under R307–403, R307–405 or R307–406.'' In addition, R307–401–3 indicates that the rules contained in R307–401 are limited to the State's minor source permitting program and are separate from major source regulations. These rules satisfy the requirements of 40 CFR 51.160(a) because R307–401–11(2)(a) provides the State or a local agency the opportunity to determine whether the project will result in a violation of applicable portions of the control strategy or interfere with attainment or maintenance of the NAAQS and 40 CFR 51.160(b) because R307–401–11(1)(h) provides a means for the State or a local agency can prevent an exempted source from violating applicable portions of the control strategy or interfering with attainment or maintenance of the NAAQS. These provisions provide important safeguards that prevent any increase that could occur as a result of replacement-in-kind from circumventing review under any other provision of the NSR program.

R307–401–11(2)(b) states that public review is not required for the update of an approval order. Since replacement-in-kind under R307–401–11 is exempt from filing a notice of intent under R307–401–5, public notice requirements under R307–401–7 do not apply.

We are proposing to disapprove R307–401–12 (Reduction in Air Contaminants). R307–401–12(1) provides that an owner or operator of a stationary source of air contaminants that reduces or eliminates air contaminants is *exempt from the approval order* requirements in R307–401–5 through R307–401–8 if the project does not increase the potential to emit of any air contaminant or cause emissions of any new air contaminant. However, the rule states in R307–401–12(1)(b) that the reduction in air contaminants is made enforceable *through an approval order* in accordance with R307–401–12(2). R307–401–12(2) states that the executive secretary will *update the sources approval order or issue a new approval order* to include the project and to make the emissions reductions enforceable.

R307–401–12 does not meet the requirements of CAA 110(a)(2)(C) and 40 CFR 51.160(a). 40 CFR 51.160(a) requires that a state or local agency must provide for enforceable procedures that enable it to determine whether a construction or modification project would result in a violation of the control strategy or interfere with attainment or maintenance of the NAAQS. As outlined above, the rules within R307–401–12 require clarification. It is not clear to the source or to the public what projects under R307–401–12 would trigger approval order requirements in R307–401–5 through R307–401–8.

We are proposing to approve R307–401–13 (Plantwide Applicability Limits). R307–401–13 provides that a plantwide applicability limit under R307–405–21 does not exempt a stationary source from the requirements in R307–401. This rule is approvable because it specifies that major PSD sources are not exempt from the requirements of R307–401.

R307–401–14 (Used Oil Fuel Burned for Energy Recovery), R307–401–15 (Air Strippers and Soil Venting Projects) and R307–401–16 (*De minimis* Emissions From Soil Aeration Projects) were previously proposed for approval (see 77 FR 37859 (June 25, 2012)). Therefore, we do not need to act on these rules in this notice.

We are proposing to approve R307–401–17 (Temporary Relocation). R307–401–17 allows temporary relocation of a stationary source for up to 180 days without submitting the proposal for public comment prior to approval or disapproval. R307–401–17 requires: (1) The executive secretary to ''evaluate the expected emissions impact at the site and (evaluate) compliance with applicable Title R307 rules as a basis for determining if approval for temporary relocation may be granted'' and (2) the owner to keep records at the site and submit the records to the executive secretary at the end of 180 calendar days, and provide that the records are made available for review. We are proposing to approve this rule because it meets the requirement of 40 CFR 51.160(a) because the rule provides the State or a local agency the opportunity to determine whether the project will result in a violation of applicable portions of the control strategy or interfere with attainment or maintenance of the NAAQS.

We are proposing to approve R307–401–18 (Eighteen Month Review). This rule provides that approval orders issued with the provisions of R307–401 will be reviewed eighteen months after the date of issuance to determine the status of the project. If the project is not proceeding, the approval order may be revoked. This rule is consistent with 40 CFR 51.160(a) because the rule provides the State or a local agency the opportunity to determine whether the project will result in a violation of applicable portions of the control strategy or interfere with attainment or maintenance of the NAAQS.

We are proposing to approve R307–401–19 (Analysis of Alternatives). R307–401–19 requires an owner or operator of a major new source or major modification that is located in a nonattainment or maintenance area or which could impact a nonattainment or maintenance area must, in addition to the requirements in R307–401, submit with the notice of intent an adequate analysis as outlined in this rule. This rule meets the requirements of 40 CFR 51.160(a) and (b) because R307–401–19 provides that an analysis, as described in this provision, must be submitted along with the notice of intent; the source must comply with all requirements in R307–401; the executive secretary shall review the analysis; and the analysis and the executive secretary's comments shall be subject to public comment as required by R307–401–7. This provision provides important safeguards that prevent any increase that could affect maintenance of the NAAQS.

We are proposing to approve R307–401–20 (Relaxation of Limitations). R307–401–20 specifies that the relaxation of limitations provision only applies to a source or modification to be located in a nonattainment or maintenance area. This rule has been previously approved in 71 FR 7679 on February 14, 2006, into R307–401–9. In this rulemaking, we are proposing to approve the renumbering of the rule ''Relaxation of Limitations'' from R307–401–9 to R307–401–20.

EPA further notes that the comparable federal definition for relaxation of limitations which applies to PSD sources, located in 40 CFR 52.21(r)(4), was incorporated by reference into the Utah SIP on July 15, 2011 (76 FR 41712). This rule is located in the Utah SIP at R307–405–19.

R307–410 (Permits: Emission Impact Analysis)

We are proposing to partially approve and partially disapprove R307–401–10 (Permits: Emission Impact Analysis).

We are proposing to approve all of R307–410, except for R307–410–5 (Documentation of Ambient Air Impacts for Hazardous Air Pollutants); we are proposing to disapprove R307–410–5 because EPA lacks authority in an action on a SIP revision under CAA section 110 to approve provisions addressing hazardous air pollutants. Thus we are proposing to disapprove these specific provisions. We are also proposing to partially approve and partially disapprove R307–410–6, as explained below.

These rules (R307–410) establish modeling requirements to determine the

impact of emissions from new or modified sources that require an approval order under R307–401. The rules are intended to ensure that the construction or modification project will not interfere with attainment or maintenance of any NAAQS as required by 40 CFR 51.160. These rules also establish the procedures and requirements for evaluating the emissions impact of hazardous air pollutants and procedures for establishing an emissions rate based on good engineering practice stack height as required by 40 CFR 51.118.

The modeling requirements for PSD permitting are incorporated by reference into R307–405; however, they appear in R307–410–3 and R307–410–4 and are not deleted from R307–410 because the same requirements still apply to smaller sources that are not subject to PSD rule requirements of R307–405. The definitions in R307–410 are deleted from R307–410–2 and incorporated by reference from 40 CFR 51.100 into R307–410–2(2). All of the definitions deleted in R307–410 are located in 40 CFR part 51.100(ff) through (kk) and (nn). The definitions of ''Vertically Restricted Emissions Release'' and ''Vertically Unrestricted Emissions Release,'' which we approved for deletion from section R307–101–2 in our prior action (73 FR 51222) have not changed; they are simply being renumbered to Rule R307–410–2 because the terms are not used in other rules. The incorporation by reference of the Federal Guidelines on Air Quality Models in R307–410–3 is updated to reflect the most current issue at the time the rules were adopted by the State. For ease of use, the modeling limit for carbon monoxide in R307–410–4, Table 1, is specified instead of referencing another rule.

The R307–410 provisions provide air impact analysis guidelines, which establish legally enforceable procedures enabling state and local agencies to determine whether construction or modification of a facility will violate applicable portions of the control strategy or interfere with attainment or maintenance of the NAAQS, which meets the requirement of 40 CFR 51.160(a).

The R307–410–6 provisions provide that the degree of emission limitation required of any source for control of any air contaminant to include determinations made under R307–401, R307–403 and R307–405, must not be affected by so much of any source's stack height that exceeds good engineering practice or by any other dispersion technique. The rule also outlines who the provisions apply to. While the rule is generally consistent with the requirements in 40 CFR 51.164 (Stack Height Procedures), similar to the disapproval discussed elsewhere in this notice regarding the 10-day public comment period, R307–410–6 is missing the required public notice elements found in 40 CFR 51.164. Specifically, R307–410–6 is missing the requirement that ''[s]uch procedures must provide that before a State issues a permit to a source based on a good engineering practice stack height that exceeds the height allowed by § 51.100(ii) (1) or (2), the State must notify the public of the availability of the demonstration study and must provide opportunity for public hearing on it''. Therefore, we are proposing to partially approve and partially disapprove this particular rule since the State rule omits the requirements for the State to notify the public of the availability of documentation of a study where a source exceeds the height allowed and provide an opportunity for public hearing.

IV. What Authorities Apply to EPA's Proposed Action

In determining whether SIP revisions submitted by the State of Utah on October 15, 2006, are approvable or not approvable, EPA applies the following authorities.

The CAA at section 110(a)(2)(C) requires states to include a minor NSR program in their SIP to regulate modifications and new construction of stationary sources within the area as necessary to assure the NAAQS are achieved. EPA's implementing regulations at 40 CFR 51.160–164 are intended to ensure that new source growth is consistent with maintenance of the NAAQS and 40 CFR 51.160(e) requires states to identify types and sizes of facilities which will be subject to review under their minor NSR program. For sources identified under 40 CFR 51.160(e), 40 CFR 51.160(a) requires that the SIP include legally enforceable procedures that enable a state or local agency to determine whether construction or modification of a facility, building, structure or installation, or combination of these will result in a violation of applicable portions of the control strategy or interference with attainment or maintenance of a national standard in the state in which the proposed source (or modification) is located or in a neighboring state. 40 CFR 51.160(b) requires these procedures must include a means by which the state or local agency can prevent a construction or modification if the construction or modification will result in a violation of applicable portions of the control strategy or interference with attainment or maintenance of a national standard.

Section 110(i) of the CAA specifically precludes states from changing the requirements of the SIP except through SIP revisions approved by EPA. SIP revisions will be approved by EPA only if they meet all requirements of section 110 of the CAA and the implementing regulations at 40 CFR part 51. See CAA section 110(l); and 40 CFR 51.104.

EPA recognizes that, under the applicable federal regulations, states have broad discretion to determine the scope of their minor NSR programs as needed to attain and maintain the NAAQS. The states have significant discretion to tailor minor NSR requirements that are consistent with the requirements of 40 CFR part 51.160. States may also provide a rationale for why their rules are at least as stringent as the 40 CFR part 51 requirements where their rules are different from those in 40 CFR part 51. For example, states may exempt from minor NSR certain categories of changes based on *de minimis* or administrative necessity grounds in accordance with the criteria set out in *Alabama Power Co.* v. *Costle,* 636 F.2d 323, 360–361 (D.C. Cir. 1979). *De minimis* sources are presumed not to have an impact and their emissions would not prevent or interfere with attainment of the NAAQS, even within nonattainment areas.

Section 110(l) of the CAA states: ''Each revision to an implementation plan submitted by a State under this Act shall be adopted by such State after reasonable notice and public hearing. The Administrator shall not approve a revision to a plan if the revision would interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171), or any other applicable requirement of this chapter.''

The states' obligation to comply with each of the NAAQS is considered as ''any applicable requirement(s) concerning attainment.'' A demonstration of noninterference is necessary to show that this revision will not interfere with attainment or maintenance of the NAAQS, including those for ozone, particulate matter, carbon monoxide (CO), sulfur dioxide (SO_2), lead, nitrogen oxides (NO_X) or any other requirement of the Act. EPA has determined that a 110(l) demonstration of noninterference is applicable to R307–401–9. Utah has submitted this demonstration (see docket).

Since there are no ambient air quality standards for hazardous air pollutants, the area's compliance with any

applicable maximum achievable control technology (MACT) standards, as well as any federal mobile source control requirements under CAA sections 112 or 202(l) would constitute an acceptable demonstration of noninterference for hazardous air pollutants.

Section 110(l) does not require a demonstration of noninterference for changes to federal requirements that are not included in the SIP. A revision to the SIP, however, cannot interfere with any federally mandated program such as a MACT standard (or related section 112 requirements).

V. EPA's Analysis of Proposed Approval Actions on SIP Revisions

In this proposed rulemaking, we are proposing to approve the new and revised rules and renumbering of rules as outlined in section III above and as described in Table 1—Rulemaking Crosswalk and Table 2—Definitions Crosswalk, located in the docket for R307–101–2, R307–401 and R307–410. We are proposing approval based on the authorities as outlined in section IV of this rulemaking. As explained in this rulemaking, the rules we are proposing to approve meet the statutory requirements of CAA section 110(a)(2)(C) and the regulatory requirements of 40 CFR 51.160.

We also evaluated the new rule R307–401–9 using CAA section 110(l). Section 110(l) provides that EPA cannot approve a SIP revision if the revision would interfere with any applicable requirement concerning attainment and RFP, or any other applicable requirement of the CAA. Therefore, EPA will approve a SIP revision only after a state has demonstrated that such a revision will not interfere (''noninterference'') with attainment of the NAAQS, RFP or any other applicable requirement of the CAA.

EPA retains the discretion to adopt approaches on a case-by-case basis to determine what the appropriate demonstration of noninterference with attainment of the NAAQS, rate of progress, RFP or any other applicable requirement of the CAA should entail. In this instance, EPA asked the State to submit an analysis showing that the approval of new section R307–401–9 would not violate section 110(l) of the CAA (see docket); this is also referred to as a ''demonstration of noninterference'' with attainment and maintenance under CAA section 110(l). Based on the state's demonstration and analysis in this notice, we are proposing to approve portions of new rule R307–401–9, as outlined in Section III above.

VI. EPA's Analysis of Proposed Disapproval Actions on SIP Revisions

We are proposing to disapprove R307–401–7 (Public Notice). This rule, which generally allows for a 10-day comment period, is inconsistent with federal regulations for Public Availability of Information found at 40 CFR 51.161(b)(2), which require at a minimum a 30-day public comment period for the permitting of a source, including minor source permits. In addition, the 30-day comment period is important to allow adequate opportunity for comment by other affected states, federal agencies, and the public.

We are proposing to disapprove R307–401–9 (Small Source Exemption) paragraph (b) and the phrase ''or (b)'' in paragraph (c). EPA lacks authority in an action on a SIP revision under CAA section 110 to approve provisions addressing hazardous air pollutants. Thus we are proposing to disapprove these specific provisions. If the State requests to withdraw these specific provisions prior to the time we take final action, we would not be obligated to take final action because these provisions would no longer be pending before the Agency as a SIP revision.

We are proposing to disapprove R307–401–12 (Reduction in Air Contaminants). As explained in this rulemaking, R307–401–12 does not meet the requirements of CAA 110(a)(2)(C) and 40 CFR 51.160(a). 40 CFR 51.160(a) requires that a state or local agency must be able to determine whether a construction or modification project would result in a violation of the control strategy or interfere with attainment or maintenance of the NAAQS. As outlined above, the rules within R307–401–12 require clarification. It is not clear to the source or to the public what projects under R307–401–12 would trigger approval order requirements in R307–401–5 through R307–401–8.

We are proposing to disapprove R307–410–5 (Documentation of Ambient Air Impacts for Hazardous Air Pollutants). EPA lacks authority in an action on a SIP revision under CAA section 110 to approve provisions addressing hazardous air pollutants. Thus we are proposing to disapprove these specific provisions. If the State requests to withdraw these specific provisions prior to the time we take final action, we would not be obligated to take final action because these provisions would no longer be pending before the Agency as a SIP revision.

We are proposing to partially approve and partially disapprove R307–410–6 (Stack Heights and Dispersion Techniques). While the rule is generally consistent with the requirements in 40 CFR 51.164 (Stack Height Procedures), similar to the disapproval discussed elsewhere in this notice regarding the 10-day public comment period, R307–410–6 is missing the required public notice elements found in 40 CFR 51.164. Specifically, R307–410–6 is missing the requirement that ''[s]uch procedures must provide that before a State issues a permit to a source based on a good engineering practice stack height that exceeds the height allowed by § 51.100(ii) (1) or (2), the State must notify the public of the availability of the demonstration study and must provide opportunity for public hearing on it''. Therefore, we are proposing to partially approve and partially disapprove this particular rule since the State rule omits the requirements for the State to notify the public of the availability of documentation of a study where a source exceeds the height allowed and provide an opportunity for public hearing.

VII. Statutory and Executive Order Reviews

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

• Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

• Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

• Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and

• Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994). In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds, Incorporation by reference.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: May 30, 2013.

Shaun L. McGrath,

Regional Administrator, Region 8.

[FR Doc. 2013–13979 Filed 6–11–13; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0360; FRL–9390–3]

Tetrachlorvinphos; Proposed Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This regulation proposes to amend the existing time-limited interim tolerances by converting them to permanent tolerances for the combined residues of the insecticide tetrachlorvinphos, including its metabolites, in or on multiple commodities identified in this document, under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: Comments must be received on or before August 12, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2011–0360, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Carmen Rodia, Registration Division (7504P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; email address: *rodia.carmen@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

• Crop production (NAICS code 111).

• Animal production (NAICS code 112).

• Food manufacturing (NAICS code 311).

• Pesticide manufacturing (NAICS code 32532).

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. Background

A detailed summary of the background related to EPA's extension of the time-limited interim tolerances for the combined residues of the insecticide tetrachlorvinphos, including its metabolites, in or on multiple commodities can be found in the **Federal Register** documents of August 14, 2002 (67 FR 52985) (FRL–7192–4); February 6, 2008 (73 FR 6867) (FRL–8345–2); September 17, 2008 (73 FR 53732) (FRL–8375–2); June 8, 2011 (76 FR 33184) (FRL–8874–7); September 16, 2011 (76 FR 57657) (FRL–8887–5); March 6, 2013 (78 FR 14487) (FRL–9380–8); and March 13, 2013 (78 FR 15880) (FRL–9380–9). The referenced documents in this unit are available in the docket for this proposed rule under

docket ID number EPA–HQ–OPP–2011–0360 at *http://www.regulations.gov.*

III. Proposal

EPA, on its own initiative, under FFDCA section 408(e), 21 U.S.C. 346a(e), is proposing to amend the existing time-limited interim tolerances by converting them to permanent tolerances for the combined residues of the insecticide tetrachlorvinphos, including its metabolites, in or on cattle, fat (of which no more than 0.1 parts per million (ppm) is tetrachlorvinphos *per se*) at 0.2 ppm; cattle, kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 1.0 ppm; cattle, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 0.5 ppm; cattle, meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*) at 2.0 ppm; cattle, meat byproducts, except kidney and liver at 1.0 ppm; egg (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 0.2 ppm; hog, fat (of which no more than 0.1 ppm is tetrachlorvinphos *per se*) at 0.2 ppm; hog, kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 1.0 ppm; hog, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 0.5 ppm; hog, meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*) at 2.0 ppm; hog, meat byproducts, except kidney and liver at 1.0 ppm; milk, fat (reflecting negligible residues in whole milk and of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 0.05 ppm; poultry, fat (of which no more than 7.0 ppm is tetrachlorvinphos *per se*) at 7.0 ppm; poultry, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*) at 2.0 ppm; poultry, meat (of which no more than 3.0 ppm is tetrachlorvinphos *per se*) at 3.0 ppm; and poultry, meat byproducts, except liver at 2.0 ppm. The existing time-limited interim tolerances in 40 CFR 180.252 expire on August 18, 2013.

As discussed in the previous rulemakings, these time-limited interim tolerances for tetrachlorvinphos, and its metabolites, have been determined to be safe based on previously submitted magnitude of residue data. (See Unit II. for citations to previously published documents concerning magnitude of residue data.) In order to support making these tolerances permanent, EPA required the submission of new magnitude of residue data. The registrant submitted livestock magnitude of residue data, storage stability data to support previously submitted magnitude of residue data in poultry and cattle, and a waiver request for the swine magnitude of residue data. Based on that data, EPA has concluded that the data confirm previous findings made by the Agency with regard to the level of residues of tetrachlorvinphos in livestock commodities and consequently, the safety finding for these tolerances.

Therefore, EPA concludes that the submitted data supports the Agency's current proposal to amend these existing time-limited tolerances to be permanent tolerances.

IV. Statutory and Executive Order Reviews

This proposed rule proposes to amend tolerances under FFDCA section 408(e). The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this proposed rule has been exempted from review under Executive Order 12866 due to its lack of significance, this proposed rule is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This proposed rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*). Nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

Pursuant to the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency previously assessed whether establishment of tolerances, exemptions from tolerances, raising of tolerance levels, expansion of exemptions, or revocations might significantly impact a substantial number of small entities and concluded that, as a general matter, these actions do not impose a significant economic impact on a substantial number of small entities. These analyses for tolerance establishments and modifications, and for tolerance revocations were published on May 4, 1981 (46 FR 24950) and on December 17, 1997 (62 FR 66020) (FRL–5753–1), respectively, and were provided to the Chief Counsel for Advocacy of the Small Business Administration. Taking into account this analysis, and available information concerning the pesticides listed in this proposed rule, the Agency hereby certifies that this proposed action will not have significant negative economic impact on a substantial number of small entities. In fact, this proposed rule will have no impact because it merely maintains the status quo by amending the existing time-limited interim tolerances by converting them to permanent tolerances. Any comments about the Agency's determination should be submitted to EPA along with comments on the proposed rule, and will be addressed prior to issuing a final rule.

In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This proposed rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this proposed rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of

regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This proposed rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this proposed rule.

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 5, 2013.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.252, revise the table in paragraph (a) to read as follows:

§ 180.252 Tetrachlorvinphos; tolerances for residues.

(a) * * *

Commodity	Parts per million
Cattle, fat (of which no more than 0.1 ppm is tetrachlorvinphos *per se*)	0.2
Cattle, kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	1.0
Cattle, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.5
Cattle, meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*)	2.0
Cattle, meat byproducts, except kidney and liver	1.0
Egg (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.2
Hog, fat (of which no more than 0.1 ppm is tetrachlorvinphos *per se*)	0.2
Hog, kidney (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	1.0
Hog, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.5
Hog, meat (of which no more than 2.0 ppm is tetrachlorvinphos *per se*)	2.0
Hog, meat byproducts, except kidney and liver	1.0
Milk, fat (reflecting negligible residues in whole milk and of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	0.05
Poultry, fat (of which no more than 7.0 ppm is tetrachlorvinphos *per se*)	7.0
Poultry, liver (of which no more than 0.05 ppm is tetrachlorvinphos *per se*)	2.0
Poultry, meat (of which no more than 3.0 ppm is tetrachlorvinphos *per se*)	3.0
Poultry, meat byproducts, except liver	2.0

* * * * *

[FR Doc. 2013–13818 Filed 6–11–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 00–175, FCC 13–69]

2000 Biennial Regulatory Review, Separate Affiliate Requirements of the Commission's Rules

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: In this document, the Commission seeks comment on the structural separation requirements of the Commission's rules, as they apply to rate-of-return carriers providing facilities-based in-region, interexchange, interstate long distance services. Specifically, the Commission seeks comment on the costs and benefits of continuing to apply requirements to rate-of-return carriers, and whether such carriers continue to have the ability and incentive to engage in anticompetitive behavior.

DATES: Comments are due on or before July 12, 2013 and reply comments are due on or before August 12, 2013.

ADDRESSES: Interested parties may submit comments, identified by CC Docket No. 00–175, by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Federal Communications Commission's Web site: http://fjallfoss.fcc.gov/ecfs2/.* Follow the instructions for submitting comments.
- *People with Disabilities:* Contact the FCC to request reasonable accommodations (accessible format documents, sign language interpreters, CART, etc.) by email: *FCC504@fcc.gov* or phone: (202) 418–0530 or TTY: (202) 418–0432.

For detailed instructions for submitting comments and additional information on the rulemaking process, see the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Gregory Kwan, Attorney Advisor, at 202–418–1191, Competition Policy Division, Wireline Competition Bureau.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Second Notice of Proposed Rulemaking* (Second FNPRM) in CC Docket No. 00–175, released on May 17, 2013. The full text of this document, which is part of the Commission's *Memorandum Opinion and Order and Report and Order and Further Notice of Proposed Rulemaking and Second Further Notice of Proposed Rulemaking,* is available for public inspection during regular business hours in the FCC Reference Center, Room CY–A257, 445 12th Street SW., Washington, DC 20554, and may also be purchased from the Commission's copy contractor, BCPI, Inc., Portals II, 445 Twelfth Street SW., Room CY–B402, Washington, DC 20554. Customers may contact BCPI, Inc. via their Web site, *http://www.bcpi.com,* or call 1–800–378–3160. This document is available in alternative formats (computer diskette, large print, audio record, and Braille). Persons with disabilities who need documents in these formats may contact the FCC by email: *FCC504@fcc.gov* or phone: 202–418–0530 or TTY: 202–418–0432. Pursuant to sections 1.415 and 1.419 of the Commission's rules, 47 CFR 1.415, 1.419, interested parties may file comments and reply comments on or before the dates indicated on the first page of this document. All pleadings are to reference CC Docket No. 00–175. Comments may be filed using the Commission's Electronic Comment Filing System (ECFS). *See Electronic Filing of Documents in Rulemaking Proceedings,* 63 FR 24121 (1998).

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the ECFS: *http://fjallfoss.fcc.gov/ecfs2/.*

• *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. If more than one docket or rulemaking number appears in the caption of this proceeding, filers must submit two additional copies for each additional docket or rulemaking number.

• Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail. All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

• All hand-delivered or messenger-delivered paper filings for the Commission's Secretary must be delivered to FCC Headquarters at 445 12th St., SW., Room TW–A325, Washington, DC 20554. The filing hours are 8:00 a.m. to 7:00 p.m. All hand deliveries must be held together with rubber bands or fasteners. Any envelopes and boxes must be disposed of *before* entering the building.

• Commercial overnight mail (other than U.S. Postal Service Express Mail and Priority Mail) must be sent to 9300 East Hampton Drive, Capitol Heights, MD 20743.

• U.S. Postal Service first-class, Express, and Priority mail must be addressed to 445 12th Street SW., Washington DC 20554.

• *People with Disabilities:* To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202–418–0530 (voice), 202–418–0432 (tty).

Synopsis of Second Further Notice of Proposed Rulemaking

1. In furtherance of our commitment to revisit rules that may be outmoded, ineffective, insufficient, or excessively burdensome, while continuing to promote competition and consumer protection consistent with the Act, we evaluate in this Second FNPRM the structural separation requirements of section 64.1903 of the Commission's rules, as they apply to rate-of-return carriers providing facilities-based in-region, interexchange, interstate long distance services (in-region long distance services). Through this proceeding, we intend to modernize our rules to reflect the competitive and marketplace realities for long distance service—at one time an expensive service, today one frequently offered on an unlimited basis by numerous facilities-based providers.

2. Section 64.1903, as written, requires independent ILECs providing long distance services using their own facilities to do so through a separate corporate subsidiary that does not jointly own transmission or switching equipment with the local exchange company. The Commission promulgated section 64.1903 against a regulatory backdrop in which local telephone service, interstate long distance, and intrastate long distance were distinct services, for which consumers often chose separate providers. Since the codification of section 64.1903 more than fifteen years ago, we have seen transformative marketplace and regulatory changes, calling into question whether the current rule is the least burdensome way to ensure that our goals of competition and consumer protection are met. The Commission has acknowledged these changes, and in 2007 granted relief to the Bell Operating Companies (BOCs) from a regulatory framework with similar structural separation requirements as section 64.1903.

3. Today, the Commission adopts the *USTelecom Forbearance Order,* which, among other things, grants the request of the United States Telecom Association (USTelecom) for forbearance from section 64.1903 as it applies to price cap carriers that comply with certain conditions. Based on the record in that proceeding, however, the *USTelecom Forbearance Order* denies similar relief to independent ILECs subject to rate-of-return regulation ''due to the continuing potential for cost misallocation.'' In this Second FNPRM, we take the next steps toward modernizing our rules for the non-BOC ILECs. Considering developments in today's marketplace, we seek comment on the costs and benefits of continuing to apply section 64.1903 to rate-of-return carriers, and whether such carriers continue to have the ability and incentive to engage in anticompetitive behavior.

4. The Commission adopted section 64.1903 based on the findings in the LEC Classification Order emphasizing the need to protect against the exercise of exclusionary market power by independent ILECs—the ability to raise rivals' costs of providing competitive services, including the misallocation of costs (for example misallocating costs from nonregulated to regulated services), non-price discrimination (for example, lower quality wholesale services provided to a competitor), and a price squeeze based on inputs that long distance competitors need, such as access services (for example, raising prices for access services, including both switched and special access, or reducing prices for retail services). In light of the market changes described above, we consider whether the rule continues to offer benefits and whether the benefits justify the regulatory burdens and costs of compliance for rate-of-return ILECs. We also recognize that market conditions alone might justify eliminating the separate affiliate requirement, at least for some independent ILECs subject to rate-of-return regulation, and seek comment on the relevant market characteristics and how they should affect our evaluation of the continued need for the separate affiliate rule.

5. *Analyzing Potential for Cost Miscalculation.* The *USTelecom Forbearance Order* granted forbearance from section 64.1903 to independent ILECs subject to price cap regulation but denied this relief to such carriers subject to rate-of-return regulation, including both independent ILECs subject to average schedules and cost companies. Rate-of-return regulation, which preceded price cap regulation, focuses on an ILEC's costs and fixes the profits an ILEC may earn based on those costs. A rate-of-return ILEC may recover only its costs plus a prescribed return on investment. Unlike price cap carriers, rate-of-return carriers are typically small, rural telephone companies concentrated in one area. Also unlike price cap carriers, non-average schedule rate-of-return independent ILEC has the ability and incentive to over allocate costs to common line and special access services because its interstate compensation for those services remains based directly on company-specific costs. We seek comment on this view. The Commission's 2011 reforms to intercarrier compensation rules cap and/or reduce interstate switched access charges, but allow increases in common line and special access rates. Thus, we believe that these changes in the access charge rules reduce, but may not eliminate, incentives for cost misallocation and potential access charge rate increases. We seek comment on this view and on the interplay between section 64.1903 and our intercarrier compensation and universal service reforms. We seek comment on whether we could address concerns about cost misallocation equally well, and in a less burdensome manner, in ways other than requiring that service be provided through a separate affiliate.

6. The Commission has previously recognized that concerns about cost misallocation are strongest when carriers provide long distance services in whole or in part through their own switching or transmission facilities. When these carriers provide long

distance service exclusively through resale, the risk of cost misallocation is reduced, and they operate pursuant to a lesser safeguard—a separate corporate division rather than a separate subsidiary. We seek comment on the extent to which rate-of-return independent ILECs provide long distance service using their own facilities. Could we deter and detect cost misallocation by requiring that independent ILECs offering long distance over their own facilities provide those services through a separate corporate division?

7. We also seek comment on whether we can reduce the burdens on average schedule carriers. Average schedule carriers are a subset of rate-of-return carriers that receive access compensation and universal service support through the use of ''average schedules'' to avoid the difficulties and expenses involved with conducting company-specific cost studies. Average schedule companies appear to have limited incentives to misallocate costs as long as they continue to use the average schedules for access compensation. However, these companies are permitted to convert to cost-based regulation without Commission approval. Thus, an average schedule company could, in theory, provide in-region long distance service without a separate affiliate, and then convert to cost-based regulation. We seek comment on how we could grant relief from the separate affiliate requirement for average schedule companies and also prevent them from misallocating costs in the future. We could condition relief from section 64.1903 on a commitment not to convert to rate-of-return regulation, or require them to reinstitute a separate affiliate if they do so. We seek comment on these and alternative suggestions. How should the Commission treat cost companies participating in NECA pools? Do these companies possess the ability and incentive to misallocate costs because disbursements from the NECA pools are based on participating companies' costs? In the *USTelecom Forbearance Order,* we grant relief to price cap carriers if they: (1) submit and obtain Bureau approval of special access performance metrics, and (2) satisfy imputation requirements, including the submission of an imputation plan for review and approval from the Bureau. Will such nonstructural safeguards obviate the need for section 64.1903, while imposing fewer costs and burdens, for rate-of-return carriers? How should our analysis for rate-of-return carriers differ, if any, from our analysis for price cap carriers?

8. *Analyzing Potential for Unlawful Non-Price Discrimination and Price Squeezes.* Section 64.1903 was intended to prevent unlawful non-price discrimination and price squeezes. Do these concerns remain relevant in light of changes in the market, including the prevalence of bundled local, intrastate long distance, and interstate long distance services? Is the separate affiliate requirement an effective, cost-effective way to prevent these anticompetitive practices? Could the Commission effectively address these concerns through ex-post facto investigations, such as under a section 208 complaint process? Are existing statutory and regulatory safeguards sufficient to deter these anticompetitive practices?

9. *Costs and Benefits of the Separate Affiliate Requirements of Section 64.1903.* How many independent ILECs use separate affiliates pursuant to section 64.1903? What costs, if any, would be saved if we eliminate section 64.1903 for independent ILECs subject to rate-of-return regulation? Would the same savings be realized if the independent ILEC were required instead to provide long distance services through a separate division? For example, what incremental costs does an independent ILEC incur in maintaining separate books of account for its long distance services, as opposed to including those costs and revenues in the accounts for its LEC operations? How does that differ depending on whether the separate books of account are for a separate division versus a separate corporation? We particularly seek empirical data on costs and burdens from independent ILECs that have experience providing long distance service through a separate corporate affiliate or a separate division so that we can analyze the differences between these structures.

10. What effect, if any, does the prohibition against joint ownership of switching and transmission equipment have on an independent ILEC's operational efficiency and ability to offer innovative services? Does that prohibition significantly limit the independent ILEC's opportunities to take advantage of economies of scope and scale associated with integrated operations? Does the prohibition make it more difficult for an independent ILEC to transform its network from a traditional Time-Division Multiplexing (TDM) network to an all-Internet Protocol (all IP) network? If so, how? Does section 64.1903 reduce independent ILECs' ability to increase telephone subscribership or extend broadband services to additional areas? If ILECs transition to offering only VoIP services, should section 64.1903 continue to apply? Finally, we seek comment on whether complying with nonstructural safeguards such as special access performance metrics and imputation requirements adequately address issues of non-price discrimination and/or price squeezes. We ask commenters to provide detailed information on the overall costs and burdens of the section 64.1903 requirements on independent ILECs and their customers.

Paperwork Reduction Act

11. This NPRM seeks comment on a potential new or revised information collection requirement. If the Commission adopts any new or revised information collection requirement, the Commission will publish a separate notice in the **Federal Register** inviting the public to comment on the requirement, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3501–3520). In addition, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the Commission seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

Initial Regulatory Flexibility Analysis

12. As required by the Regulatory Flexibility Act of 1980, as amended (RFA), the Commission has prepared this Supplemental Initial Regulatory Flexibility Analysis (Supplemental IRFA) of the possible significant economic impact on a substantial number of small entities by the policies proposed in this Second NPRM. Written comments are requested on this Supplemental IRFA. Comments must be identified as responses to the Supplemental IRFA and must be filed by the deadlines for comments on the Second FNPRM. The Commission will send a copy of the Second FNPRM, including this Supplemental IRFA, to the Chief Counsel for Advocacy of the Small Business Administration (SBA). In addition, the Second FNPRM and Supplemental IRFA (or summaries thereof) will be published in the **Federal Register**.

13. *Purpose of the Proposed Rules.* In the Second FNPRM, we explore the costs and benefits of continuing to apply the structural separation requirements contained in section 64.1903 of the Commission's rules, 47 CFR 64.1903, to

independent incumbent local exchange carriers (ILECs) subject to rate-of-return regulation and providing in-region, interexchange, interstate long distance services (in-region long distance services) in today's marketplace.

14. In the Second FNPRM, we seek comments addressing marketplace changes such as the decline of stand-alone long distance services, the rise of facilities-based ''all-distance services'' competition from cable and wireless, and the role of bundles in today's long distance market. We therefore seek comment addressing whether incentives for anticompetitive behavior exist for independent ILECs subject to rate-of-return regulation, and whether granting relief from section 64.1903 is appropriate.

15. *Legal Basis.* The legal basis for any action that may be taken pursuant to the Second FNPRM is contained in sections 4(i), 4(j), 10, 201 through 204, 214, 220(a), and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 154(i), 154(j), 160, 201 through 204, 214, 220(a), and 303(r).

16. *Description and Estimate of the Number of Small Entities to Which the Proposed Rules Will Apply.* RFA directs agencies to provide a description of and, where feasible, an estimate of the number of small entities that may be affected by the proposed rules, if adopted. The RFA generally defines the term ''small entity'' as having the same meaning as the terms ''small business,'' ''small organization,'' and ''small governmental jurisdiction.'' In addition, the term ''small business'' has the same meaning as the term ''small-business concern'' under the Small Business Act. A small-business concern'' is one which: (1) is independently owned and operated; (2) is not dominant in its field of operation; and (3) satisfies any additional criteria established by the SBA.

17. *Small Businesses.* Nationwide, there are a total of approximately 27.5 million small businesses, according to the SBA.

18. *Wired Telecommunications Carriers.* The SBA has developed a small business size standard for Wired Telecommunications Carriers, which consists of all such companies having 1,500 or fewer employees. According to Census Bureau data for 2007, there were 3,188 firms in this category, total, that operated for the entire year. Of this total, 3144 firms had employment of 999 or fewer employees, and 44 firms had employment of 1000 employees or more. Thus, under this size standard, the majority of firms can be considered small.

19. *Incumbent Local Exchange Carriers (ILECs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to incumbent local exchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 1,307 carriers reported that they were incumbent local exchange service providers. Of these 1,307 carriers, an estimated 1,006 have 1,500 or fewer employees and 301 have more than 1,500 employees. Consequently, the Commission estimates that most providers of incumbent local exchange service are small businesses that may be affected by rules adopted pursuant to the Second FNPRM.

20. We have included small incumbent LECs in this present RFA analysis. As noted above, a ''small business'' under the RFA is one that, inter alia, meets the pertinent small business size standard (e.g., a telephone communications business having 1,500 or fewer employees), and ''is not dominant in its field of operation.'' The SBA's Office of Advocacy contends that, for RFA purposes, small incumbent LECs are not dominant in their field of operation because any such dominance is not ''national'' in scope. We have therefore included small incumbent LECs in this RFA analysis, although we emphasize that this RFA action has no effect on Commission analyses and determinations in other, non-RFA contexts.

21. *Interexchange Carriers (IXCs).* Neither the Commission nor the SBA has developed a size standard for small businesses specifically applicable to interexchange services. The closest applicable size standard under SBA rules is for Wired Telecommunications Carriers. Under that size standard, such a business is small if it has 1,500 or fewer employees. According to Commission data, 359 companies reported that their primary telecommunications service activity was the provision of interexchange services. Of these 359 companies, an estimated 317 have 1,500 or fewer employees and 42 have more than 1,500 employees. Consequently, the Commission estimates that the majority of interexchange service providers are small entities that may be affected by rules adopted pursuant to the Order.

22. *Description of Projected Reporting, Recordkeeping, and Other Compliance Requirements for Small Entities.* In this Second FNPRM, the Commission proposes additional or modified information collections that would impose reporting and recordkeeping on current independent ILECs subject to rate-of-return regulation, including small entities. Specifically, the Second FNPRM invites comment on whether the Commission should replace its legacy framework for the provision of in-region, interstate long distance services provided by independent ILECs subject to rate-of-return regulation with a framework more closely tailored to the needs of consumers and competitors in today's marketplace. The central feature of this proposal is to amend or eliminate the application of section 64.1903 to independent ILECs subject to rate-of-return regulation.

23. Based on these questions, the Commission anticipates that a record will be developed concerning actual burdens and alternative ways in which the Commission could lessen the burdens on small entities subject to these requirements throughout the nation.

24. *Steps Taken to Minimize the Significant Economic Impact on Small Entities, and Significant Alternatives Considered.* The RFA requires an agency to describe any significant, specifically small business, alternatives that it has considered in reaching its proposed approach, which may include the following four alternatives (among others): ''(1) the establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities; (2) the clarification, consolidation, or simplification of compliance and reporting requirements under the rules for such small entities; (3) the use of performance rather than design standards; and (4) an exemption from coverage of the rule, or any part thereof, for such small entities.''

25. The overall objective of this proceeding is to reduce regulatory burdens on independent ILECs to the extent consistent with the public interest, and is part of the Commission's ongoing efforts under Executive Order 13,579 to revisit ''rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned.'' The Second FNPRM seeks specific proposals as to which existing regulations might be removed or streamlined in their application to provision of in-region, interstate and international interexchange services by independent ILECs subject to rate-of-return regulation absent current safeguards, and asks parties to comment

on whether such independent ILECs should continue to be classified as nondominant in the provision of such services if section 64.1903 is repealed. The Second FNPRM also asks parties to discuss whether, and to what extent, dominant carrier regulation is aptly suited to achieving the Commission's objectives to promote competition and to deter anticompetitive behavior by independent ILECs subject to rate-of-return regulation. The Second FNPRM seeks comment on these matters, especially as they might affect small entities subject to the rules.

26. *Federal Rules that May Duplicate, Overlap, or Conflict with the Proposed Rules.* None.

Ex Parte Presentations

27. This proceeding shall be treated as a ''permit-but-disclose'' proceeding in accordance with the Commission's ex parte rules. Persons making ex parte presentations must file a copy of any written presentation or a memorandum summarizing any oral presentation within two business days after the presentation (unless a different deadline applicable to the Sunshine period applies). Persons making oral ex parte presentations are reminded that memoranda summarizing the presentation must (1) list all persons attending or otherwise participating in the meeting at which the ex parte presentation was made, and (2) summarize all data presented and arguments made during the presentation. If the presentation consisted in whole or in part of the presentation of data or arguments already reflected in the presenter's written comments, memoranda or other filings in the proceeding, the presenter may provide citations to such data or arguments in his or her prior comments, memoranda, or other filings (specifying the relevant page and/or paragraph numbers where such data or arguments can be found) in lieu of summarizing them in the memorandum. Documents shown or given to Commission staff during ex parte meetings are deemed to be written ex parte presentations and must be filed consistent with section 1.1206(b). In proceedings governed by section 1.49(f) or for which the Commission has made available a method of electronic filing, written ex parte presentations and memoranda summarizing oral ex parte presentations, and all attachments thereto, must be filed through the electronic comment filing system available for that proceeding, and must be filed in their native format (e.g., .doc, .xml, .ppt, searchable .pdf). Participants in this proceeding should familiarize themselves with the Commission's ex parte rules.

Ordering Clauses

28. Accordingly, *it is ordered* that, pursuant to Sections 1, 2, 4(i), 4(j), 201 through 205, 220(a), 251, 272, and 303(r) of the Communications Act of 1934, as amended, 47 U.S.C. 151, 152, 154(i), 154(j), 201 through 205, 220(a), 251, 272, and 303(r) this Second Further Notice of Proposed of Rulemaking in CC Docket No. 00–175 *is adopted.*

29. *It is further ordered* that the Commission's Consumer and Governmental Affairs Bureau, Reference Information Center, *shall send* a copy of this Second Further Notice of Proposed Rulemaking in CC Docket No. 00–175, including the Initial Regulatory Flexibility Certifications, to the Chief Counsel for Advocacy of the Small Business Administration.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2013–13976 Filed 6–11–13; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF ENERGY

48 CFR Parts 925, 952, and 970

RIN 1991–AB99

Acquisition Regulations: Export Control

AGENCY: Department of Energy.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Department of Energy (DOE) is proposing to amend the Department of Energy Acquisition Regulation (DEAR) to add export control requirements applicable to the performance of DOE contracts.

DATES: Written comments on this proposed rulemaking must be received on or before close of business July 12, 2013

ADDRESSES: You may submit comments, identified by ''DEAR: Export Control and RIN 1991–AB99,'' by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Email to: DEARrulemaking@hq.doe.gov.* Include DEAR: Export Control and RIN 1991–AB99 in the subject line of the message.
- *Mail to:* U.S. Department of Energy, Office of Acquisition and Project Management, MA–611, 1000 Independence Avenue SW., Washington, DC 20585. Comments by email are encouraged.

FOR FURTHER INFORMATION CONTACT: Lawrence Butler, (202) 287–1945 or *lawrence.butler@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

I. Executive Summary
A. Purpose and Legal Authority
B. Summary of Major Provisions
1. Part 925—Foreign Acquisition
2. Part 952—Solicitation Provisions and Contract Clauses
3. Part 970—DOE Management and Operating Contracts
II. Summaries of Export Control Laws
III. Procedural Requirements
A. Review Under Executive Order 12866
B. Review Under Executive Order 12988
C. Review Under the Regulatory Flexibility Act
D. Review Under the Paperwork Reduction Act
E. Review Under the National Environmental Policy Act
F. Review Under Executive Order 13132
G. Review Under the Unfunded Mandates Reform Act of 1995
H. Review Under the Treasury and General Government Appropriations Act, 1999
I. Review Under Executive Order 13211
J. Review Under the Treasury and General Government Appropriations Act, 2001
K. Review Under Executive Order 13609
L. Approval by the Office of the Secretary of Energy

I. Executive Summary

A. Purpose and Legal Authority

The purpose of this rulemaking is to add new DEAR subparts 925.71 and 970.2571 to set forth requirements concerning compliance with export control laws, regulations and directives applicable to the performance of DOE contracts.

Export control laws, regulations and directives that may apply to a contract in effect on the date of the contract award and as amended subsequently include, but are not limited to: the Atomic Energy Act of 1954, as amended; the Arms Export Control Act (22 U.S.C. 2751 et seq.); the Export Administration Act of 1979 (50 U.S.C. app. 2401 et seq.), as continued under the International Emergency Economic Powers Act (Title II of Pub. L. 95–223, 91 Stat. 1626, October 28, 1977); Trading with the Enemy Act (50 U.S.C. App. 5(b) as amended by the Foreign Assistance Act of 1961); Assistance to Foreign Atomic Energy Activities (10 Code of Federal Regulations (CFR) part 810); Export Administration Regulations (15 CFR parts 730 through 774); International Traffic in Arms Regulations (22 CFR parts 120 through 130); Export and Import of Nuclear Equipment and Material (10 CFR part 110); regulations administered by the Office of Foreign Assets Control (31 CFR

Subtitle B Chapter V); the Espionage Act (37 U.S.C. 791 et seq.); DOE Order 142.3A, Unclassified Foreign Visits and Assignments Program; DOE Order 551.1D, Official Foreign Travel; and DOE Order 580.1A, Department of Energy Personal Property Management Program.

The list of laws and regulations is the same as that in the Export Restriction Notice in 41 CFR 109–1.5303(b)(6), with updated citations for revised versions, as appropriate. The Export Restriction Notice is required by 41 CFR part 109 for all transfers, sales or other offerings of High Risk Personal Property (HRPP), which includes all export-controlled items. The DOE directives in the list are the three DOE orders that refer to export compliance when performing Contractor activities. DOE solicits comment on whether additional export control laws, regulations or directives should be added to this list. Descriptions of these laws, regulations and directives are provided in section II.

B. Summary of Major Provisions

DOE proposes to amend the DEAR as follows, for consistency with a 2010 amendment to the Department of Defense Acquisition Regulations (DFARS) (DFARS Case 2004–D010, 75 FR 18030, Apr. 8, 2010):

1. Part 925—Foreign Acquisition

Part 925 is amended by adding new section 925.71 to set forth requirements for contractors concerning the export control of items, including but not limited to unclassified information, materials, technology, equipment or software.

More information on what constitutes an ''item'', as well as export control requirements generally, can be found at the following Department of Commerce (DOC) Web site: *http://www.bis.doc.gov/licensing/exportingbasics.htm.* Points of contact for DOC are also provided at this Web site. Points of contact and additional information for the Department of State can be found at *http://www.pmddtc.state.gov/about/key_personnel.html* and *http://www.pmddtc.state.gov/documents/ddtc_getting_started.pdf.* Points of contact and additional information for the Department of Treasury can be found at *http://www.treasury.gov/services/Pages/Foreign-Transaction-Licensing-and-Reporting.aspx.* Points of contact and additional information for the Nuclear Regulatory Commission can be found at *http://www.nrc.gov/about-nrc/ip/export-import.html.* The point of contact for the Department of Energy is the Office of Nonproliferation and International Security in the National Nuclear Security Administration at *http://nnsa.energy.gov/aboutus/ourprograms/nonproliferation/programoffices/officenonproliferationinternationalsecurity.*

DOE contractors are responsible for complying with export control requirements applicable to their contracts. DOE requirements for contractors will be set forth in a new DEAR Export Clause. It is the contractor's responsibility to comply with all applicable laws and regulations regarding export-controlled items. This responsibility exists independent of, and is not established, or limited by, this DEAR rulemaking.

2. Part 952—Solicitation Provisions and Contract Clauses

Part 952 is amended by adding new clause 952.225–XX to set forth requirements for DOE contractors concerning compliance with applicable export control laws, regulations and directives, including a requirement for DOE contractors to obtain the necessary licenses, approvals and relevant documentation to comply with these applicable laws, regulations and directives.

3. Part 970—DOE Management and Operating Contracts

Subpart 970.25 is amended by adding new section 970.2571 to set forth requirements for management and operating contractors concerning export control of items, including but not limited to unclassified information, materials, technology, equipment or software.

As noted above, more information on what constitutes an ''item'', as well as export control requirements generally, can be found at the following DOC Web site: *http://www.bis.doc.gov/licensing/exportingbasics.htm.* Points of contact for DOC are also provided at this Web site. Points of contact and additional information for the Department of State can be found at *http://www.pmddtc.state.gov/about/key_personnel.html* and *http://www.pmddtc.state.gov/documents/ddtc_getting_started.pdf.* Points of contact and additional information for the Department of Treasury can be found at *http://www.treasury.gov/services/Pages/Foreign-Transaction-Licensing-and-Reporting.aspx.* Points of contact and additional information for the Nuclear Regulatory Commission can be found at *http://www.nrc.gov/about-nrc/ip/export-import.html.* The point of contact for the Department of Energy is the Office of Nonproliferation and International Security in the National Nuclear Security Administration at *http://nnsa.energy.gov/aboutus/ourprograms/nonproliferation/programoffices/officenonproliferationinternationalsecurity.* DOE management and operating contractors are responsible for complying with export control requirements applicable to their contracts. DOE requirements for management and operating contractors will be set forth in a new DEAR Export Clause. It is the contractor's responsibility to comply with all applicable laws and regulations regarding export-controlled items. This responsibility exists independent of, and is not established, or limited by, this DEAR rulemaking.

Subpart 970.52 is amended by adding new clause 970.5225–1 to set forth requirements for management and operating contractors concerning compliance with export control laws, regulations and directives, including a requirement for DOE management and operating contractors to obtain the necessary licenses, approvals and relevant documentation to comply with applicable laws, regulations and directives.

II. Summaries of Export Control Laws, Regulations and Directives

Brief summaries of each of these authorities—which are independent of, and not limited by, any DEAR policy or clause—are set forth below:

Atomic Energy Act of 1954, as Amended (AEA)

The AEA empowers DOE to authorize persons subject to the jurisdiction of the United States to engage directly or indirectly in the production of special nuclear material outside of the United States.

Arms Export Control Act

Provides the authority to control the export of defense articles and services, and charges the President to exercise this authority. Executive Order 11958, as amended, delegated this statutory authority to the Secretary of State.

Export Administration Act (EAA)

Provides legal authority to the President to control, for reasons of national security, foreign policy and/or short supply, the export and reexport of items that are subject to the Export Administration Regulations (EAR) (see below). The EAA has expired but has been continued under the International Emergency Economic Powers Act.

International Emergency Economic Powers Act

Authorizes the President to regulate commerce after declaring a national emergency in response to any unusual

and extraordinary threat to the United States which has a foreign source.

Trading With the Enemy Act

Restricts trade with countries hostile to the United States. The law gives the President the power to oversee or restrict any and all trade between the U.S. and its enemies in times of war. The scope of the TWEA was expanded by the Foreign Assistance Act of 1961.

Foreign Assistance Act of 1961

Restricts assistance to any government which engages in a consistent pattern of gross violations of internationally recognized human rights.

10 CFR Part 810, ''Assistance to Foreign Atomic Energy Activities''

The DOE has jurisdictional authority over exports of unclassified nuclear technology under section 57 b.(2) of the Atomic Energy Act of 1954, as amended.

10 CFR Part 110, ''Export and Import of Nuclear Equipment and Material''

The Nuclear Regulatory Commission (NRC) has jurisdictional authority for exports for peaceful nuclear purposes of nuclear reactors, nuclear enrichment and reprocessing facilities, heavy water production facilities, related proprietary operation and maintenance manuals, and related equipment. The NRC also has jurisdictional authority for exports of special nuclear material, source material, byproduct material, deuterium, and nuclear grade graphite for nuclear end use.

Export Administration Regulations (EAR)

The Department of Commerce (DOC) has jurisdictional authority over a broad range of dual-use commodities (items that have both commercial and potentially military applications), and items that are not controlled by other export regimes. Items that are subject to the EAR include items found on the Commerce Control List (CCL), where they are grouped into ten categories. These include, among other things, certain electronics, computers, sensors and lasers, and microorganisms and toxins. Items on the CCL are classified based upon their physical characteristics and their potential uses. Items not listed on the CCL may nevertheless be subject to the EAR. Such items are designated ''EAR99.'' An export license may be required for an item subject to the EAR if the export of the item could impact U.S. national security or foreign policy objectives.

International Traffic in Arms Regulations (ITAR)

The Arms Export Control Act is implemented through the ITAR. The Department of State (State) has jurisdictional authority over munitions items, including military systems, equipment, components, and services, and space-related systems, equipment, components, services and items.

Treasury Department (Treasury): Foreign Asset Control Regulations

The Trading with the Enemy Act is implemented through the Foreign Asset Control Regulations. The Treasury Office of Foreign Asset Control (OFAC) has jurisdictional authority over all financial and tangible items having a destination to embargoed and terrorist sponsoring states.

Department of Energy: Unclassified Foreign Visits and Assignments Program

Defines a program for unclassified foreign national access to DOE sites, information, and technologies by establishing review, approval, documenting and tracking requirements.

Department of Energy: Official Foreign Travel

Establishes DOE and National Nuclear Security Administration (NNSA) requirements and responsibilities governing official foreign travel by Federal and contractor employees.

Department of Energy: Personal Property Management Program

Sets forth (a) requirements that implement and supplement Public Laws, Executive Orders, Office of Management and Budget directives, and any other agency issuances affecting the DOE's personal property management program; (b) requirements that reflect the accountability perspective of property management; (c) policy that assists DOE property managers, contracting and financial managers, and other DOE officials in understanding their property management roles and responsibilities; and (d) standards, practices, and performance expectations for property management.

This rulemaking, which would add new requirements to DEAR part 925 and subpart 970.25, and create new clauses in part 952 and subpart 970.52, addresses concerns raised in DOE Inspector General (IG) Reports issued in 2004 and 2007. In the 2004 report, the DOE IG determined that the two DOE contractors it reviewed were not properly applying export control procedures. The DOE IG further stated that DOE must ensure that export control guidance, including deemed export guidance, is disseminated and consistently implemented throughout the DOE complex. In the 2007 report, the DOE IG recommended expedited actions to ensure compliance with export control requirements throughout the DOE complex. This rule also addresses a 2011 Government Accountability Office (GAO) report in which the GAO identified weaknesses in government-wide export controls.

III. Procedural Requirements

A. Review Under Executive Orders 12866 and 13563

Today's regulatory action has been determined to be a ''significant regulatory action'' under Executive Order 12866, ''Regulatory Planning and Review,'' 58 FR 51735 (October 4, 1993). Accordingly, this proposed rule was reviewed by the Office of Information and Regulatory Affairs within the Office of Management and Budget.

DOE has also reviewed this regulation pursuant to Executive Order 13563, issued on January 18, 2011 (76 FR 3281 (Jan. 21, 2011)). Executive Order 13563 is supplemental to and explicitly reaffirms the principles, structures, and definitions governing regulatory review established in Executive Order 12866. To the extent permitted by law, agencies are required by Executive Order 13563 to: (1) Propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

DOE emphasizes as well that Executive Order 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as

possible. In its guidance, the Office of Information and Regulatory Affairs has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. DOE believes that today's NOPR is consistent with these principles, including the requirement that, to the extent permitted by law, agencies adopt a regulation only upon a reasoned determination that its benefits justify its costs and, in choosing among alternative regulatory approaches, those approaches maximize net benefits.

B. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction.

With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, these proposed regulations meet the relevant standards of Executive Order 12988.

C. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. Neither 5 U.S.C. 553 nor 41 U.S.C. 418(b) requires that today's proposed rule be proposed for public comment. No regulatory flexibility analysis has been prepared.

D. Review Under the Paperwork Reduction Act

This proposed rule does not impose a collection of information requirement subject to the Paperwork Reduction Act, 44 U.S.C. 3501 et seq.

E. Review Under the National Environmental Policy Act

DOE has concluded that promulgation of this proposed rule falls into a class of actions which would not individually or cumulatively have significant impact on the human environment, as determined by DOE's regulations (10 CFR part 1021, subpart D) implementing the National Environmental Policy Act (NEPA) of 1969 (42 U.S.C. 4321 et seq.). Specifically, this proposed rule is categorically excluded from NEPA review because the amendments to the DEAR are strictly procedural (categorical exclusion A6). Therefore, this proposed rule does not require an environmental impact statement or environmental assessment pursuant to NEPA.

F. Review Under Executive Order 13132

Executive Order 13132, 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. Agencies are required to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and carefully assess the necessity for such actions. DOE has examined today's rule and has determined that it does not preempt State law and does not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. No further action is required by Executive Order 13132.

G. Review Under the Unfunded Mandates Reform Act of 1995

The Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) generally requires a Federal agency to perform a detailed assessment of costs and benefits of any rule imposing a Federal Mandate with costs to State, local or tribal governments, or to the private sector, of $100 million or more. This rulemaking does not impose a Federal mandate on State, local or tribal governments or on the private sector.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277), requires Federal agencies to issue a Family Policymaking Assessment for any rule or policy that may affect family well being. This rule will have no impact on family well-being. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'', 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution and use. Today's rule is not a significant energy action. Accordingly, DOE has not prepared a Statement of Energy Effects.

J. Review Under the Treasury and General Government Appropriations Act, 2001

The Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for agencies to review most disseminations of information to the public under implementing guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed today's notice under the OMB and DOE guidelines and has concluded

that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13609

Executive Order 13609 of May 1, 2012, ''Promoting International Regulatory Cooperation,'' requires that, to the extent permitted by law and consistent with the principles and requirements of Executive Order 13563 and Executive Order 12866, each Federal agency shall:

(a) If required to submit a Regulatory Plan pursuant to Executive Order 12866, include in that plan a summary of its international regulatory cooperation activities that are reasonably anticipated to lead to significant regulations, with an explanation of how these activities advance the purposes of Executive Order 13563 and this order;

(b) Ensure that significant regulations that the agency identifies as having significant international impacts are designated as such in the Unified Agenda of Federal Regulatory and Deregulatory Actions, on *RegInfo.gov,* and on *Regulations.gov;*

(c) In selecting which regulations to include in its retrospective review plan, as required by Executive Order 13563, consider:

(i) Reforms to existing significant regulations that address unnecessary differences in regulatory requirements between the United States and its major trading partners, consistent with section 1 of this order, when stakeholders provide adequate information to the agency establishing that the differences are unnecessary; and

(ii) Such reforms in other circumstances as the agency deems appropriate; and

(d) For significant regulations that the agency identifies as having significant international impacts, consider, to the extent feasible, appropriate, and consistent with law, any regulatory approaches by a foreign government that the United States has agreed to consider under a regulatory cooperation council work plan.

DOE has reviewed this proposed rule under the provisions of Executive Order 13609 and determined that the rule complies with all requirements set forth in the order.

L. Approval by the Office of the Secretary of Energy

The Office of the Secretary of Energy has approved issuance of this proposed rule.

List of Subjects in 48 CFR Parts 925, 952 and 970

Government procurement.

Issued in Washington, DC, on May 24, 2013.

Paul Bosco,

Director, Office of Acquisition and Project Management, Department of Energy.

Oliver M. Voss,

Acting Director, Office of Acquisition Management, National Nuclear Security Administration.

For reasons set out in the preamble, the DOE is proposing to amend Chapter 9 of Title 48 of the Code of Federal Regulations as set forth below.

PART 925—FOREIGN ACQUISITION

■ 1. The authority citation for part 925 continues to read as follows:

Authority: 42 U.S.C. 7101 et seq., and 50 U.S.C. 2401 et seq.

■ 2. Subpart 925.71 is added to read as follows:

Subpart 925.71—Export Control

Sec.
925.7100 Scope of subpart.
925.7101 Policy.
925.7102 Contract clause.

Subpart 925.71—Export Control

925.7100 Scope of subpart.

This subpart implements Department of Energy (DOE) requirements for contractors concerning export control of items including but not limited to unclassified information, materials, technology, equipment or software.

925.7101 Policy.

(a) DOE and its contractors must comply with applicable laws, regulations and directives when exporting items, included but not limited to, unclassified information, materials, technology, equipment, or software. DOE therefore requires its contractors to comply with all applicable export control laws, regulations, and directives, in effect on the date of contract award and as amended subsequently, including but not limited to: the Atomic Energy Act of 1954, as amended; the Arms Export Control Act (22 U.S.C. 2751 et seq.); the Export Administration Act of 1979 (50 U.S.C. app. 2401 et seq.), as continued under the International Emergency Economic Powers Act (Title II of Pub. L. 95–223, 91 Stat. 1626, October 28, 1977; 50 U.S.C. 1701 et seq.); Trading with the Enemy Act; (50 U.S.C. App. 5(b) as amended by the Foreign Assistance Act of 1961); Assistance to Foreign Atomic Energy Activities (Title 10 of the Code of Federal Regulations (CFR) part 810); Export Administration Regulations (15 CFR parts 730 through 774); International Traffic in Arms Regulations (22 CFR parts 120 through 130); Export and Import of Nuclear Equipment and Material (10 CFR part 110); regulations administered by the Office of Foreign Assets Control (31 CFR Subtitle B Chapter V); the Espionage Act (37 U.S.C. 791 et seq.); DOE Order 142.3A, Unclassified Foreign Visits and Assignments Program, October 14, 2010; DOE Order 551.1D, Official Foreign Travel, June 24, 2008; and DOE Order 580.1A, Department of Energy Personal Property Management Program, March 30, 2012; and the Espionage Act (37 U.S.C. 791 et seq.) which among other things, prohibit—

(1) The making of false statements and concealment of any material information regarding the use or disposition, export or re-export of property; and

(2) Any use or disposition, export or re-export of property which is not authorized in accordance with the provisions of any transfer, sale or other offering.

(b) Contractors seeking guidance on how to comply with export control requirements should review the list of laws, regulations and directives applicable to the export of unclassified information, materials, technology, equipment or software set forth in paragraph (a) of this section and in clause 952.225–XX. Contractors also may contact the agencies responsible for administration of export laws, regulations or directives applicable to a particular export (e.g., Departments of State, Commerce, Treasury, and Energy, or the Nuclear Regulatory Commission). Questions regarding DOE Directives should be referred to the appropriate DOE program office.

(c) It is the contractor's responsibility to comply with all applicable laws and regulations regarding export-controlled items. This responsibility exists independent of, and is not established, or limited by, this subpart.

925.7102 Contract clause.

The contracting officer shall insert the clause at 952.225–XX, Compliance with export control laws, regulations and directives (Export Clause), in any contract that may involve the export of items, including but not limited to unclassified information, materials, technology, equipment, or software.

PART 952—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

■ 3. The authority citation for part 952 continues to read as follows:

Authority: 42 U.S.C. 2201; 2282a; 2282b; 2282c; 42 U.S.C. 7101 et seq.; 50 U.S.C. 2401 et seq.

■ 4. Section 952.225–XX is added to read as follows:

952.225–XX Compliance with export control laws, regulations and directives (Export Clause).

As prescribed in section 925.7102, insert the following clause:

COMPLIANCE WITH EXPORT CONTROL LAWS, REGULATIONS AND DIRECTIVES (XXX 20XX)

(a) The Contractor shall comply with applicable laws, regulations and directives regarding the export of items, including but not limited to unclassified information, materials, technology, equipment or software related to the performance of this contract. The Contractor may be subject to civil or criminal penalties or contractual remedies for non-compliance with applicable laws, regulations and directives as set forth in such laws, regulations and directives, including monetary fines, imprisonment, or contract termination.

(b) The Contractor's responsibility to comply with all applicable laws and regulations regarding export-controlled items exists independent of, and is not established, or limited by, the information provided by this clause.

(c) The following Export Restriction Notice shall be included in all transfers, sales or other offerings of unclassified information, materials, technology, equipment or software pursuant to a DOE contract:

[Start of Export Restriction Notice]

Export Restriction Notice—The use, disposition, export, and re-export of this property are subject to export control laws, regulations and directives, in effect on the date of contract award and as amended subsequently, that include but are not limited to: the Atomic Energy Act of 1954, as amended; the Arms Export Control Act (22 U.S.C. 2751 et seq.); the Export Administration Act of 1979 (50 U.S.C. app. 2401 et seq.) as continued under the International Emergency Economic Powers Act (Title II of Pub.L. 95–223, 91 Stat. 1626, October 28, 1977; 50 U.S.C. 1701 et seq.); Trading with the Enemy Act (50 U.S.C. App. 5(b) as amended by the Foreign Assistance Act of 1961); Assistance to Foreign Atomic Energy Activities (10 CFR part 810); Export and Import of Nuclear Equipment and Material (10 CFR part 110); International Traffic in Arms Regulations (22 CFR parts 120 through 130); Export Administration Regulations (15 CFR parts730 through 734); regulations administered by the Office of Foreign Assets Control (31 CFR parts 500 through 598); DOE Order 142.3A, Unclassified Foreign Visits and Assignments Program, October 14, 2010; DOE Order 551.1D, Official Foreign Travel, June 24, 2008; and DOE Order 580.1A, Department of Energy Personal Property Management Program, March 30, 2012; and the Espionage Act (37 U.S.C. 791 et seq.) which among other things, prohibit—

(1) The making of false statements and concealment of any material information regarding the use or disposition, export or re-export of the property; and

(2) Any use or disposition, export or re-export of the property which is not authorized in accordance with the provisions of this agreement.

[End of Export Restriction Notice]

(d) Upon a request for guidance by the Contractor, the Contracting Officer should direct the Contractor to the agency responsible for administration of the export laws, regulations or directives applicable to the Contractor's question.

(e) The Contractor shall obtain the necessary licenses, approvals and relevant documentation to comply with applicable export control laws, regulations and directives. The Contractor shall notify the Contracting Officer in a timely manner, in writing, of:

(1) Any export control requirements it has determined apply to contract performance; and

(2) That it has taken appropriate steps to comply with such requirements.

(f) The Contractor's responsibility to comply with all applicable export control laws, regulations and directives exists independent of, and is not established or limited by, this clause.

(g) Nothing in the terms of this contract adds to, changes, supersedes, or waives any of the requirements of applicable Federal laws, Executive Orders, and regulations.

(h) The Contractor shall include this clause in subcontracts at any tier that involve the transfer, sale or other offering of items, including but not limited to unclassified information, materials, technology, equipment or software.

(End of clause)

PART 970—DOE MANAGEMENT AND OPERATING CONTRACTS

■ 5. The authority citation for part 970 continues to read as follows:

Authority: 42 U.S.C. 2201; 2282a; 2282b; 2282c; 42 U.S.C. 7101 et seq.; 50 U.S.C. 2401 et seq.

■ 6. Subpart 970.25 is revised to read as follows:

Subpart 970.25—Foreign Acquisition

Sec.
970.2570 Buy American Act.
970.2570–1 Contract clause.
970.2571 Export control.
970.2571–1 Scope of subpart.
970.2571–2 Policy.
970.2571–3 Contract clause.

Subpart 970.25—Foreign Acquisition

970.2570 Buy American Act.

970.2570–1 Contract clause.

Contracting officers shall insert the clauses at 48 CFR 52.225–1, Buy American Act— Supplies, and 48 CFR 52.225–9, Buy American Act—Construction Materials, in management and operating contracts. The clause at 48 CFR 52.225–1 shall be modified in paragraph (d) of the FAR by substituting the word ''use'' for the word ''deliver.''

970.2571 Export control.

970.2571–1 Scope of subpart.

This subpart implements requirements concerning the export by DOE management and operating contractors of unclassified information, materials, technology, equipment or software.

970.2571–2 Policy.

(a) DOE and its contractors must comply with applicable laws, regulations and directives when exporting unclassified information, materials, technology, equipment or software DOE therefore requires its contractors to comply with all applicable export control laws, regulations, and directives, in effect on the date of contract award and as amended subsequently, including but not limited to: the Atomic Energy Act of 1954, as amended; the Arms Export Control Act (22 U.S.C. 2751 et seq.); the Export Administration Act of 1979 (50 U.S.C. app. 2401 et seq.) as continued under the International Emergency Economic Powers Act (Title II of Pub. L. 95–223, 91 Stat. 1626, October 28, 1977; 50 U.S.C. 1701 et seq.); Trading with the Enemy Act; (50 U.S.C. App. 5(b) as amended by the Foreign Assistance Act of 1961); Assistance to Foreign Atomic Energy Activities (Title 10 of the Code of Federal Regulations (CFR) part 810); Export Administration Regulations (15 CFR parts 730 through 774); International Traffic in Arms Regulations (22 CFR parts 120 through 130); Export and Import of Nuclear Equipment and Material (10 CFR part 110); regulations administered by the Office of Foreign Assets Control (31 CFR parts 500 through 598); the Espionage Act (37 U.S.C. 791 et seq.); DOE Order 142.3A, Unclassified Foreign Visits and Assignments Program, October 14, 2010; DOE Order 551.1D, Official Foreign Travel, June 24, 2008; and DOE Order 580.1A, Department of Energy Personal Property Management Program, March 30, 2012; and the Espionage Act (37 U.S.C. 791 et seq.) which among other things, prohibit—

(1) The making of false statements and concealment of any material information regarding the use or disposition, export or re-export of property; and

(2) Any use or disposition, export or re-export of property which is not authorized in accordance with the provisions of any transfer, sale or other offering.

(b) Contractors seeking guidance on how to comply with export control requirements should review the list of laws, regulations and directives applicable to the export of unclassified information, materials, technology, equipment or software set forth in paragraph (a) above and in clause 970.5225–1. Contractors also may contact the agencies responsible for administration of export laws, regulations or directives applicable to a particular export (e.g., Departments of State, Commerce, Treasury and Energy, or the Nuclear Regulatory Commission). Questions regarding DOE Directives should be referred to the appropriate DOE program office.

(c) It is the Contractor's responsibility to comply with all applicable laws and regulations regarding export-controlled items. This responsibility exists independent of, and is not established, or limited by, this subpart.

970.2571–3 Contract clause.

The contracting officer shall insert the clause at 970.5225–1, Compliance with export control laws, regulations and directives (Export Clause), in any contract that may involve the export of items including but not limited to unclassified information, materials, technology, equipment or software.

■ 7. Section 970.5225–1 is added to read as follows:

Subpart 970.52—Solicitation Provisions and Contract Clauses for Management and Operating Contracts

970.5225–1 Compliance with export control laws, regulations and directives (Export Clause).

As prescribed in section 970.2571–3, insert the following clause:

COMPLIANCE WITH EXPORT CONTROL LAWS, REGULATIONS AND DIRECTIVES (XXX 20XX)

(a) The Contractor shall comply with applicable laws, regulations and directives regarding the export of items including but not limited to unclassified information, materials, technology, equipment or software related to the performance of this contract. The Contractor may be subject to civil or criminal penalties for non-compliance with applicable laws, regulations and directives, as set forth in such laws, regulations and directives, including contract termination, monetary fines and/or imprisonment.

(b) The Contractor's responsibility to comply with all applicable laws and regulations regarding export-controlled items exists independent of, and is not established, or limited by, the information provided by this clause.

(c) The following Export Restriction Notice shall be included in all transfers, sales or other offerings of unclassified information, materials, technology, equipment or software:

[Start of Export Restriction Notice]

Export Restriction Notice—The use, disposition, export, and re-export of this property are subject to export control laws, regulations and directives, in effect on the date of contract award and as amended subsequently, that include but are not limited to: the Atomic Energy Act of 1954, as amended; the Arms Export Control Act (22 U.S.C. 2751 et seq.); the Export Administration Act of 1979 (50 U.S.C. app. 2401 et seq.), as continued under the International Emergency Economic Powers Act (Title II of Pub.L. 95–223, 91 Stat. 1626, October 28, 1977; 50 U.S.C. 1701 et seq.); Trading with the Enemy Act (50 U.S.C. App. 5(b) as amended by the Foreign Assistance Act of 1961); Assistance to Foreign Atomic Energy Activities (10 CFR part 810); Export and Import of Nuclear Equipment and Material (10 CFR part 110); International Traffic in Arms Regulations (22 CFR parts 120 through 130); Export Administration Regulations (15 CFR parts 730 through 734); regulations administered by the Office of Foreign Assets Control (31 CFR Subtitle B Chapter V); DOE Order 142.3A, Unclassified Foreign Visits and Assignments Program, October 14, 2010; DOE Order 551.1D, Official Foreign Travel, June 24, 2008; and DOE Order 580.1A, Department of Energy Personal Property Management Program, March 30, 2012; and the Espionage Act (37 U.S.C. 791 et seq.) which among other things, prohibit:

(1) The making of false statements and concealment of any material information regarding the use or disposition, export or re-export of the property; and

(2) Any use or disposition, export or re-export of the property which is not authorized in accordance with the provisions of this agreement.

[End of Export Restriction Notice]

(d) Upon a request for guidance by the Contractor, the Contracting Officer should direct the Contractor to the agency responsible for the administration of the export laws, regulations or directives applicable to the Contractor's question.

(e) The Contractor shall obtain the necessary licenses, approvals and relevant documentation to comply with applicable export control laws, regulations and directives. The Contractor shall notify the Contracting Officer in a timely manner, in writing, of 1) any export control requirements it has determined apply to contract performance, and 2) that it has taken appropriate steps to comply with such requirements.

(f) The Contractor's responsibility to comply with all applicable export control laws, regulations and directives exists independent of, and is not established or limited by this clause.

(g) Nothing in the terms of this contract adds to, changes, supersedes, or waives any of the requirements of applicable Federal laws, Executive Orders, and regulations.

(h) The Contractor shall include this clause in subcontracts at any tier that involve the transfer, sale or other offering of items including but not limited to unclassified information, materials, technology, equipment, or software.

(End of clause)

[FR Doc. 2013–13798 Filed 6–11–13; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R9–ES–2010–0086; 4500030115]

RIN 1018–AZ52

Endangered and Threatened Wildlife and Plants; Listing All Chimpanzees as Endangered

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule and 12-month petition finding.

SUMMARY: We, the U.S. Fish and Wildlife Service, propose to list all chimpanzees (*Pan troglodytes*) as endangered under the Endangered Species Act of 1973, as amended (Act). We are taking this action in response to a petition to list the entire species, whether in the wild or in captivity, as endangered under the Act. This proposal constitutes our 12-month finding on the petition and announces our finding that listing all chimpanzees as endangered is warranted. This document also serves as our 5-year

review of the species. If we finalize this rule as proposed, we would eliminate the separate classification of captive and wild chimpanzees under the Act and extend the Act's protections to captive chimpanzees in the United States. In addition, we propose to amend the special rule for primates to remove chimpanzees from the rule. If the listing of all chimpanzees as endangered is finalized, the provisions of the special rule can no longer be applied to captive chimpanzees. We seek comments from the public on this proposed rule.

DATES: We will consider comments and information received or postmarked on or before August 12, 2013. Comments submitted electronically using the Federal eRulemaking Portal (see **ADDRESSES**, below) must be received by 11:59 p.m. Eastern Time on the closing date.

We must receive requests for public hearings, in writing, at the address shown in **FOR FURTHER INFORMATION CONTACT** by July 29, 2013.

ADDRESSES: You may submit information by one of the following methods:

(1) *Electronically:* Go to the Federal eRulemaking Portal: *http://www.regulations.gov.* In the Search box, enter FWS–R9–ES–2010–0086, which is the docket number for this rulemaking. You may submit a comment by clicking on ''Comment Now!'' If your comments will fit in the provided comment box, please use this feature of *http://www.regulations.gov,* as it is most compatible with our comment review procedures. If you attach your comments as a separate document, our preferred file format is Microsoft Word. If you attach multiple comments (such as form letters), our preferred format is a spreadsheet in Microsoft Excel.

(2) *By hard copy:* Submit by U.S. mail or hand-delivery to: Public Comments Processing, Attn: FWS–R9–ES–2010–0086; Division of Policy and Directives Management; U.S. Fish and Wildlife Service; 4401 N. Fairfax Drive, MS 2042–PDM; Arlington, VA 22203.

We request that you send comments only by the methods described above. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see Information Requested under **SUPPLEMENTARY INFORMATION** for more information).

FOR FURTHER INFORMATION CONTACT: Janine Van Norman, Chief, Branch of Foreign Species, Endangered Species Program, U.S. Fish and Wildlife Service, 4401 North Fairfax Drive, Room 420, Arlington, VA 22203; telephone 703–358–2171. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose of the Regulatory Action

We are proposing to list all chimpanzees, whether in the wild or in captivity, as endangered under the Endangered Species Act of 1973, as amended (Act). We have determined that the Act does not allow for captive-held animals to be assigned separate legal status from their wild counterparts on the basis of their captive state, including through designation as a separate distinct population segment (DPS). It is also not possible to separate out captive-held specimens for different legal status under the Act by other approaches. Therefore, we are proposing to eliminate the separate classification of chimpanzees held in captivity and list the entire species, wherever found, as endangered under the Act.

II. Major Provision of the Regulatory Action

If adopted as proposed, this action will eliminate separate classifications for wild and captive chimpanzees under the Act. All chimpanzees, whether in the wild or in captivity, will be listed as one entity that is endangered in the List of Endangered and Threatened Wildlife at 50 CFR 17.11(h). This action will also remove the chimpanzee and paragraph (c)(3) from the special rule for primates, found at 50 CFR 17.40(c), extending the Act's protections to all chimpanzees.

Background

Section 4(b)(3)(B) of the Endangered Species Act (Act) (16 U.S.C. 1531 *et seq.*) requires that, for any petition to revise the Federal Lists of Endangered and Threatened Wildlife and Plants that contains substantial scientific or commercial information that listing the species may be warranted, we make a finding within 12 months of the date of receipt of the petition (''12-month finding''). In this finding, we determine whether the petitioned action is: (a) Not warranted, (b) warranted, or (c) warranted, but immediate proposal of a regulation implementing the petitioned action is precluded by other pending proposals to determine whether species are endangered or threatened, and expeditious progress is being made to add or remove qualified species from the Federal Lists of Endangered and Threatened Wildlife and Plants. We must publish these 12-month findings in the **Federal Register**.

In this document, we announce that listing all chimpanzees, whether in the wild or in captivity, as endangered is warranted, and are proposing to revise the entry of this species in the Federal List of Endangered and Threatened Wildlife. Additionally, this action, if finalized as proposed, will eliminate a special rule under section 4(d) of the Act that exempts captive chimpanzees in the United States from the general prohibitions of the Act.

Prior to issuing a final rule on this proposed action, we will take into consideration all comments and any additional information we receive. Such information may lead to a final rule that differs from this proposal. All comments and recommendations, including names and addresses of commenters, will become part of the administrative record.

Petition History

On March 16, 2010, we received a petition dated the same day, from Meyer Glitzenstein & Crystal on behalf of The Humane Society of the United States, the American Association of Zoological Parks and Aquariums, the Jane Goodall Institute, the Wildlife Conservation Society, the Pan African Sanctuary Alliance, the Fund for Animals, Humane Society International, and the New England Anti-Vivisection Society (hereafter referred to as ''petitioners'') requesting that captive chimpanzees (*Pan troglodytes*) be reclassified as endangered under the Act. The petition clearly identified itself as such and included the requisite identification information for the petitioners, as required by 50 CFR 424.14(a). The petition contained information on what the petitioners reported as potential threats to the species from habitat loss, poaching and trafficking, disease, and inadequate regulatory mechanisms. In a September 15, 2010, letter to Katherine Meyer, we responded that we were required to complete a significant number of listing and critical habitat actions, including complying with court orders and court-approved settlement agreements, that required nearly all of our listing and critical habitat funding for fiscal year 2010. We also stated that we anticipated making an initial finding during fiscal year 2011, as to whether the petition contained substantial information indicating that the action may be warranted.

On October 12, 2010, we received a letter from Anna Frostic, Staff Attorney with the Humane Society of the United States, on behalf of the petitioners clarifying that the March 16, 2010, petition was a petition to list the entire species (*Pan troglodytes*) as endangered,

whether in the wild or in captivity, pursuant to the Act. We acknowledged receipt of this letter in a letter to Ms. Frostic dated October 15, 2010.

Previous Federal Actions

On October 19, 1976, we published in the **Federal Register** a rule listing the chimpanzee and 25 other species of primates under the Act (41 FR 45990); the chimpanzee and 13 of the other primate species were listed as threatened. The chimpanzee was found to be threatened based on (1) Commercial logging and clearing of forests for agriculture and the use of arboricides; (2) capture and exportation for use in research labs and zoos; (3) diseases, such as malaria, hepatitis, and tuberculosis contracted from humans; and (4) ineffectiveness of existing regulatory mechanisms. We simultaneously issued a special rule that the general prohibitions provided to the threatened species would apply except for live animals of these species held in captivity in the United States on the effective date of the rulemaking, progeny of such animals, or the progeny of animals legally imported into the United States after the effective date of the rulemaking.

On November 4, 1987, we received a petition from the Humane Society of the United States, World Wildlife Fund, and Jane Goodall Institute, requesting that the chimpanzee be reclassified from threatened to endangered. On March 23, 1988 (53 FR 9460), we published in the **Federal Register** a finding, in accordance with section 4(b)(3)(A) of the Act, that the petition had presented substantial information indicating that the requested reclassification may be warranted and initiated a status review. We opened a comment period, which closed July 21, 1988, to allow all interested parties to submit comments and information.

On December 28, 1988 (53 FR 52452), we published in the **Federal Register** a finding that the requested reclassification was warranted with respect to chimpanzees in the wild. This decision was based on the petition and subsequent supporting comments that dealt primarily with the status of the species in the wild and not with the viability of captive populations. We did not propose reclassification of captive chimpanzees. We found that the special rule exempting captive chimpanzees in the United States from the general prohibitions may encourage propagation, providing surplus animals and reducing the incentive to remove animals from the wild. On February 24, 1989 (54 FR 8152), we published in the **Federal Register** a proposed rule to implement such reclassification. Following publication of the proposed rule, we opened a 60-day comment period to allow all interested parties to submit comments and information.

On March 12, 1990, we published in the **Federal Register** (55 FR 9129) a final rule reclassifying the wild populations of the chimpanzees as endangered. The captive chimpanzees remained classified as threatened, and those within the United States continued to be covered by the special rule allowing activities otherwise prohibited.

On September 1, 2011, we published in the **Federal Register** a finding that the March 16, 2010, petition (discussed above under ''Petition History'') presented substantial scientific or commercial information indicating that the requested action may be warranted, and we initiated a status review (76 FR 54423).

On November 1, 2011, we published in the **Federal Register** a notice correcting an incorrect Docket Number given under the **ADDRESSES** section of the September 1, 2011, petition finding. We also gave notice that we were making the large volume of supporting documents submitted with the petition available to the public. To allow the public adequate time to review the supporting documents, we extended the period of time for submitting information to January 30, 2012 (74 FR 67401).

5-Year Review

Section 4(c)(2)(A) of the Act requires that we conduct a review of listed species at least once every 5 years. A 5-year review is conducted to ensure that the classification of a listed species is appropriate. Section 4(c)(2)(B) requires that we determine on the basis of this review: (1) Whether a species no longer meets the definition of endangered or threatened and should be removed from the List (delisted); (2) whether a species more properly meets the definition of threatened and should be reclassified from endangered to threatened; or (3) whether a species more properly meets the definition of endangered and should be reclassified from threatened to endangered. This 12-month finding serves as our 5-year review of this species.

Information Requested

We intend that any final action resulting from this proposed rule be based on the best scientific and commercial data available. Therefore, we seek comments and information on this proposed rule, particularly but not limited to:

(1) Information on taxonomy, distribution, habitat selection, diet, and population abundance and trends of this species.

(2) Information on the effects of habitat loss and changing land uses on the distribution and abundance of this species and its principal food sources over the short and long term.

(3) Information on whether changing climatic conditions are affecting the species, its habitat, or its prey base.

(4) Information on the effects of other potential threat factors, including live capture and collection, domestic and international trade, predation by other animals, and diseases of this species.

(5) Information on management programs for chimpanzee conservation, including mitigation measures related to conservation programs, and any other private or governmental conservation programs that benefit this species.

(6) Information relevant to whether any populations of this species may qualify as distinct population segments.

(7) Information on captive breeding and domestic trade of this species in the United States.

(8) The factors that are the basis for making a listing determination for a species under section 4(a) of the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1531 *et seq.*), which are:

(a) The present or threatened destruction, modification, or curtailment of its habitat or range;

(b) Overutilization for commercial, recreational, scientific, or educational purposes;

(c) Disease or predation;

(d) The inadequacy of existing regulatory mechanisms; or

(e) Other natural or manmade factors affecting its continued existence.

Please include sufficient information with your submission (such as full references) to allow us to verify the information you provide. Submissions merely stating support for or opposition to the action under consideration without providing supporting information, although noted, will not be considered in making a determination. Section 4(b)(1)(A) of the Act directs that determinations as to whether any species is an endangered or threatened species must be made ''solely on the basis of the best scientific and commercial data available.''

You may submit your information concerning this proposed rule by one of the methods listed in **ADDRESSES**. If you submit information via *http://www.regulations.gov,* your entire submission—including any personal identifying information—will be posted on the Web site. If your submission is

made via hardcopy that includes personal identifying information, you may request at the top of your document that we withhold this personal identifying information from public review. However, we cannot guarantee that we will be able to do so. We will post all hardcopy submissions on *http://www.regulations.gov.*

Public Hearing

At this time, we do not have a public hearing scheduled for this proposed rule. The main purpose of most public hearings is to obtain public testimony or comment. In most cases, it is sufficient to submit comments through the Federal eRulemaking Portal, described above in the **ADDRESSES** section. If you would like to request a public hearing for this proposed rule, you must submit your request, in writing, to the person listed in **FOR FURTHER INFORMATION CONTACT** by the date specified above in **DATES**.

Evaluation of Listable Entities

Under section 3(16) of the Act, we may consider for listing any species, which includes subspecies of fish, wildlife, and plants, or any distinct population segment (DPS) of vertebrate fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). Such entities are considered eligible for separate listing status under the Act (and, therefore, referred to as listable entities) should we determine that they meet the definition of an endangered species or threatened species.

The Service was petitioned to list all chimpanzees, whether in the wild or in captivity, as endangered. Essentially, this request is to eliminate the separate classification of captive chimpanzees from chimpanzees located in the wild. This petition raised questions regarding whether the Service has any discretion to differentiate the listing status of specimens in captivity from those in the wild.

The Service has not had an absolute policy or practice with respect to this issue, but generally has included wild and captive animals together when it has listed species. The example set by the separate chimpanzee listings was used as support for two petitions the Service received in 2010 to delist U.S. captive and U.S. captive-bred members of three antelope species in the United States. In the 2005 listing determination for the scimitar-horned oryx (*Oryx dammah*), dama gazelle (*Gazella dama*), and addax (*Addax nasomaculatus*) (70 FR 52310, September 2, 2005), the Service found that a differentiation in the listing status of captive specimens of these antelopes in the United States was not appropriate. The petitioners, Exotic Wildlife Association, Safari Club International, and Safari Club International Foundation, asserted that the treatment by the Service of chimpanzees in 1990 warrants similar treatment now for these antelope species. Because the Service has not formally stated whether the current statute, regulations, and applicable policies provide any discretion to differentiate the listing status of specimens in captivity from those in the wild, we reviewed the issues raised by these petitions to ensure the Act is implemented appropriately.

As discussed below, we find that the Act does not allow for captive-held animals to be assigned separate legal status from their wild counterparts on the basis of their captive state, including through designation as a separate distinct population segment (DPS).[1] It is also not possible to separate out captive-held specimens for different legal status under the Act by other approaches (see *Other Potential Approaches for Separate Legal Status*).

Provisions of the Act

The legal mandate of section 4(a)(1) is to determine ''whether any *species* is an endangered species or threatened species. . . .'' (emphasis added). In the Act, a ''species'' is defined to include any subspecies and any DPS of a vertebrate animal, as well as taxonomic species. Other than a taxonomic species or subspecies, captive-held specimens (of a vertebrate animal species) would have to qualify as a ''distinct population segment . . . which interbreeds when mature'' to qualify as a separate DPS.[2] Nothing in the plain language of the definitions of ''endangered species,'' ''threatened species,'' or ''species'' expressly indicates that captive-held animals can or cannot have separate status under the Act on the basis of their state of captivity. However, certain language in the Act is inconsistent with a determination of separate legal status for captive-held animals.

Under section 4(c)(1), the agency is to specify for each species listed ''over what portion of its range'' it is endangered or threatened.[3] ''Range,'' while not defined in the Act, consistently has been interpreted as that general geographical area where the species is found *in the wild.* Thus, a group of animals held solely in captivity and analyzed as a separate listable entity has no ''range'' separate from that of the species to which it belongs, at least as that term has been applied under the Act. The Service has consistently interpreted ''range'' in the Act as a geographical area where the species is found *in the wild.*

As demonstrated in various species' listings at 50 CFR 17.11 and 17.12, information in the ''Historic Range'' column is the range of the species in the wild. For none of these species does the ''range'' information include countries or geographic areas on the basis of where specimens are held in captivity, even though the Service knows that specimens of many of these species have long been held in facilities outside their native range, including in the United States.

Also, in analyzing the ''present or threatened destruction, modification, or curtailment of [a species'] habitat or *range''* (emphasis added) (see section 4(a)(1)(A) of the Act), the Service has traditionally analyzed habitat threats in the native range of wild specimens and not included other geographic areas where specimens have been moved to and are being held in captivity. We are not aware of any Service listing decision where analysis of threats to the ''range'' has included geographic areas outside the native range where specimens are held in captivity.

In analyzing other threats to a species (see sections 4(a)(1)(B), 4(a)(1)(C), 4(a)(1)(D), and 4(a)(1)(E) of the Act), the Service has also limited its analysis to threats acting upon wild specimens within the native range of the species, and has not included analysis of ''threats'' to animals held in captivity except as those threats impact the potential for the captive population to contribute to recovery of the species in the geographic area where wild specimens are native.

Finally, the Service's 2011 draft policy on the meaning of the phrase

[1] As compared to populations that exist in the wild, ''captivity'' is defined as ''living wildlife . . . held in a controlled environment that is intensively manipulated by man for the purpose of producing wildlife of the selected species, and that has boundaries designed to prevent animal [sic], eggs or gametes of the selected species from entering or leaving the controlled environment. General characteristics of captivity may include but are not limited to artificial housing, waste removal, health care, protection from predators, and artificially supplied food'' (50 CFR 17.3).

[2] The analysis in this document addresses only situations where it is not disputed that the specimens are members of a wildlife species. This analysis does not address situations where members of a species have been held in captivity for a sufficiently long period that they have developed into a separate domesticated form of the species, including where the domesticated form is sufficiently distinct to be considered a separate taxonomic species or subspecies (e.g., domesticated donkey vs. the African wild ass).

[3] Even though the Service has taken the position in its draft SPR policy (76 FR 76987) that the range information called for under section 4(c)(1) is for information purposes, this statutory language still informs the question of Congress' intent under the statute.

''significant portion of its range'' (SPR) (76 FR 76987; December 9, 2011) defines ''range'' as the ''general geographic area within which that species can be found at the time the Service or National Marine Fisheries Service (NMFS) makes any particular status determination. This range includes those areas used throughout all or part of the species' life cycle, even if they are not used regularly (e.g., seasonal habitat). Lost historical range in relevant to the analysis of the status of the species, but it cannot consitutute a significant portion of a species' range. The ''general geographic area within which the species can be found'' is broad enough to include geographic areas where animals have been moved by humans and are being held in captivity. However, the Service has not applied the definition in this manner in the past and does not intend to do so in the future. SPR analyses have been and will be limited to geographic areas where specimens are found in the wild.

In addition to the use of ''range'' in sections 4(a)(1) and 4(c)(1), the definitions of ''endangered species'' and ''threatened species,'' found in section 3 of the Act, also discuss the role of the species range in listing determinations. The Act defines an endangered species as ''any species which is in danger of extinction throughout all or a significant portion of its range,'' and a threatened species as ''any species which is likely to become an endangered species . . . throughout all or a significant portion of its range.'' As noted above, ''range'' has consistently been interpreted by the Service as being the natural range of the species *in the wild*.[4] For all the reasons discussed above, a group of animals held in captivity could not have separate legal status under the Act because they have no ''range,'' that is separate from the range of the species in the wild to which they belong as that term is used in the Act.

Certain provisions in sections 9 and 10 of the Act show that what Congress intended was that captive-held animals would generally have the same legal status as their wild counterparts by providing certain exceptions for animals held in captivity. Section 9(b)(1) of the Act provides an exemption from certain section 9(a)(1) prohibitions for listed animals held in captivity or in a controlled environment as of the date of the species listing (or enactment of the Act), provided the holding in captivity and any subsequent use is not in the course of a commercial activity. Section 9(b)(2) of the Act provides an exemption from all section 9(a)(1) prohibitions for raptors held in captivity or in a controlled environment as of 1978 and their progeny. Section 10(a)(1)(A) of the Act allows permits to ''enhance the *propagation* or survival'' of the species (emphasis added). This demonstrates that Congress recognized the value of captive-holding and propagation of listed specimens held in captivity, but intended that such specimens would be protected under the Act, with these activities generally regulated by permit.[5] If captive-held specimens could simply be excluded through the listing process, none of these exceptions and permits would have been needed.

Purpose of the Act

Meaning of Section 2(b) of the Act

The full purposes of the Act, stated in section 2(b), are ''to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved [hereafter referred to as the first purpose], to provide a program for the conservation of such endangered species and threatened species [hereafter referred to as the second purpose], and to take such steps as may be appropriate to achieve the purposes of the treaties and conventions set forth in subsection (a) of this section [hereafter referred to as the third purpose]''. It has been stated, without explanation, that the language of section 2(b) of the Act supports protecting only specimens that occur in the wild. However, the purposes listed in section 2(b) indicate that the three provisions are intended to have independent meaning, with little to indicate that Congress' intent was to protect only specimens of endangered or threatened species found in the wild. The treaties and conventions under the third purpose are expressly those listed in section 2(a)(4) of the Act, all of which are for the protection of wildlife and plants, and none of which are limited to protection of endangered or threatened specimens in the wild.[6] The first purpose calls for conservation of ecosystems, independent of conservation of species themselves (which is separately listed as the second purpose). This does focus on protection of native habitats (those inhabited by the species in the wild in its native range), as it is generally the ecosystems or habitats within which a species has evolved that are those upon which it ''depends.'' However, the phrase ''upon which endangered species and threatened species depend'' indicates only that ecosystem (i.e., habitat) protection should be focused on that used by endangered and threatened species, and does not indicate that the sole focus of the Act is conservation of species within their native ecosystems. Several provisions in the Act provide authority to protect habitat, independent of authorities applicable to protection and regulation of specimens of listed species themselves. See, for example, section 5 (Land Acquisition), section 6 (Cooperation With the States), section 7 (Interagency Cooperation), and section 8 (International Cooperation).

It is the second purpose under section 2(b) of the Act that speaks to the conservation of species themselves that are endangered or threatened. However, nothing in the language of the second purpose indicates that conservation programs should be limited to specimens located in the wild. The plain language of section 2(b) refers to ''species,'' with no distinction between wild specimens of the species as compared to captive-held specimens of the species. Thus, nothing in the plain language indicates that captive-held specimens should be excluded from the Act's processes and protections that would contribute to recovery (i.e., ''conservation'') of the entire taxonomic species. It is true that the phrasing of the second purpose (''to provide a program for the conservation of *such* endangered species and threatened species'' (emphasis added)) links the second purpose of species recovery to the first

[4] *See also* Endangered Species Act: Hearings on H.R. 37, H.R. 470, H.R. 471, H.R. 1461, H.R. 1511, H.R. 2669, H.R. 2735, H.R. 3310, H.R. 3696, H.R. 3795, H.R. 4755, H.R. 2169 and H.R. 4758 Before the House Subcomm. on Fisheries and Wildlife Conservation and the Environment, House Comm. on Merchant Marine and Fisheries, 93d Cong. 198 (1973) (hereinafter 1973 Hearing on H.R. 37 and others) (Letter from S. Dillon Ripley, Secretary of Smithsonian Institute, to Chairman, House Comm. on Merchant Marine and Fisheries, April 23, 1973 (lauding H.R. 4758, the Administration's legislative proposal that contained a definition of ''endangered species'' substantially similar to the statutory definition eventually adopted by Congress in the 1973 Act: ''In effect the bill offers a great deal of flexibility by providing that a species may be placed on the list if the Secretary determines that it is presently threatened with extinction, not only in all of its *natural* range, but in a significant part thereof, as well.'') (emphasis added)).

[5] *See* Endangered Species Conservation Act of 1972: Hearing on S. 249, S. 3199 and S. 3818 Before the Senate Subcomm. on the Environment, Senate Comm. on Commerce, 92nd Cong. 211–12 (1972) (statement of Deborah Appel, Assistant to the Director for Public Information, National Audubon Society) (endorsing S. 3199, a bill considered by the Senate that contained similar language eventually adopted by Congress in the purpose section of the 1973 Act, but advising against a specific mandate requiring captive propagation because''the capture of specimens for experiment in captive propagation may in itself endanger the chances of some rare species for survival in the wild.'').

[6] Nor are these treaties and conventions limited to protection of species listed as endangered or threatened under the Act.

purpose of ecosystem (i.e., native habitat) protection, thus making the *goal* of the statute recovery of endangered and threatened species in their natural ecosystems. But there is nothing in the phrasing to indicate that the specific provisions of the statute for meeting this goal should be limited to specimens of the species located within the ecosystems upon which they depend.

Separate Legal Status Is Inconsistent With Section 2(b)

The potential consequences of captive-held specimens being given separate legal status under the Act on the basis of their captive state, particularly where captive-held specimens would have no legal protection while wild specimens are listed as endangered or threatened,[7] indicate that such separate legal status is not consistent with the section 2(b) purpose of conserving endangered and threatened species. Congress specifically recognized ''overutilization for commercial, recreational, scientific, or educational purposes'' as a potential threat that contributes to the risk of extinction for many species. If captive-held specimens could have separate legal status under the Act, the threat of overutilization would likely increase. For example, the taxonomic species would potentially be subject to increased take and trade in ''laundered'' wild-caught specimens to feed U.S. or foreign market demand because protected wild specimens would be generally indistinguishable from unprotected captive-held specimens. Because there would be no restriction or regulation on the taking, sale, import, export, or transport in the course of commercial activities in interstate or foreign commerce of captive specimens by persons subject to U.S. jurisdiction, there would be a potential legal U.S. market in captive-held endangered or threatened specimens and their progeny operating parallel to any illegal U.S. market (or U.S. citizen participation in illegal foreign markets) in wild specimens. With the difficulty of distinguishing captive-held from wild specimens, especially when they are broken down into their parts and products, illegal wild specimens of commercial value could likely easily be passed off as legal captive specimens and thus be traded as legal specimens.

If captive-held specimens could have separate legal status under the Act, the taxonomic species would potentially be subject to increased take of animals from the wild and illegal transfer of wild specimens into captivity. The United States is one of the world's largest markets for wildlife and wildlife products.[8] Poachers and smugglers would have increased incentive to remove animals from the wild and smuggle them into captive-holding facilities in the United States for captive propagation or subsequent commercial use of either live or dead specimens, because once in captivity there would be no Act restrictions on use of the captive-held specimens or their offspring. This would be a particular issue for foreign species where States regulate native wildlife (and therefore captive-held domestic endangered or threatened specimens would continue to be regulated under State law), but often do not regulate use of nonnative wildlife. This could be a particularly lucrative trade for poachers and smugglers because many endangered and threatened species (particularly foreign species) are at risk of extinction because of their high commercial value in trade (as trophies or pets, or for their furs, horns, ivory, shells, or medicinal or decorative use).

Congress included the similarity-of-appearance provision in section 4(e) to allow the Service to regulate species under the Act where one species so closely resembles an endangered or threatened species that enforcement cannot distinguish between the protected and unprotected species and this difficulty is a threat to the species. The Service's only option in the cases of ''take'' described above would be to complete separate similarity-of-appearance listings for captive-held animals. A similarity-of-appearance listing under the Act for captive-held specimens would make captive specimens subject to the same restrictions as listed wild specimens.

Operation of Key Provisions of the Act

As described in the following subsections, operation of key provisions in sections 4 and 7 of the Act also indicate that it would not be consistent with Congressional intent or the purpose of the Act to treat groups of captive-held specimens as separate listable entities on the basis of their captive state.

Section 4: Listing Captive-Held Specimens

The section 4 listing process is not well suited to analyzing threats to an entirely captive-held group of specimens that are maintained under controlled, artificial conditions.

If wild populations and captive-held specimens could qualify as separate listable entities, and it was determined that captive-held specimens do not qualify as endangered or threatened, captive-held specimens would receive no assistance or protection under the Act even in cases where wild populations continue to decline, even to the point of the species being extirpated in the wild, with the specimens in captivity being the only remaining members of the species and survival of the species being dependent on the survival of the captive-held specimens. This would not be consistent with the purposes of the Act.

Groupings of captive-held specimens might not meet the definition of endangered or threatened under the statutory factors because the scope of the section 4 analysis for a captive-specimen listing would be the conditions under which the captive-held specimen exists, not the conditions of the members of the species in the wild, as the captive-held members of the species and wild members of the species would be under separate consideration for listing under the Act and therefore under separate 5-factor analyses. Groupings of solely captive-held specimens might not meet the definition of endangered (in danger of extinction throughout all or a significant portion of their range) or threatened (likely to become endangered within the foreseeable future) when the conditions for individual specimens' survival are carefully controlled under human management, especially for species that readily breed in captivity, where breeding has resulted in large numbers of genetically diverse specimens, or where there are no known uncontrollable threats such as disease.

The majority of the section 4(a)(1) factors would be difficult to apply to captive-held specimens with a range independent of wild specimens because they are not readily suited to evaluating specimens held in captivity or might contribute to a determination that the entity under consideration (separate groupings of captive-held specimens) does not qualify as endangered or threatened. There may be situations where only disease threats (factor C) and other natural or manmade factors (factor E) would be applicable to consideration of purely captive-held groups of

[7] If it were determined that captive-held animals can have separate legal status on the basis of their captive state, proponents of separate legal status could argue that these captive specimens do not qualify as endangered or threatened species because they do not face ''threats'' that create a substantial risk of extinction to the captive specimens such as those faced by the wild population (see *Section 4: Listing Captive-held Specimens*).

[8] See USFWS Office of Law Enforcement Annual Report for FY 2009 p. 7.

specimens. The present or threatened destruction, modification, or curtailment of habitat or range (factor A) may not be a threat for a listable entity consisting solely of captive-held specimens, because the physical environment under which captive specimens are held is generally readily controllable and, in many cases, optimized to ensure the physical health of the animal. Overutilization (factor B) is unlikely to be a factor threatening the continued existence of groups of captive-held specimens where both breeding and culling are managed to ensure the continuation of stock at a desired level based on ownership interest and market demand. Predation (factor C) may rarely be a factor for captive-held specimens because predators may be more readily controlled. Human management may provide for all essential life functions, thereby eliminating selection or competition for mates, food, water resources, and shelter.

It is unclear how the ''inadequacy of existing regulatory mechanisms'' (factor D) would apply to captive-held specimens with a range independent of wild specimens because this factor generally applies in relationship to threats identified under the other factors. Regulatory mechanisms applicable to wild specimens usually include measures to protect natural habitat and laws that regulate activities such as take, sale, and import and export. However, there might be no regulatory mechanisms applicable when the group of specimens under consideration is in captivity (except perhaps general humane treatment or animal health laws).

That the section 4 process is not well suited to listings of entirely captive specimens is demonstrated by the previous listing action for the chimpanzee. The chimpanzee was originally listed in its entirety as a threatened species (41 FR 45990; Oct. 19, 1976). On March 12, 1990 (55 FR 9129), the Service reclassified wild populations of chimpanzees as a separate endangered species, noting that wild populations had declined due to massive habitat destruction, excessive hunting and capture by people, and lack of effective national and international controls. But the final reclassification rule never analyzed whether the newly designated DPS consisting of chimpanzees ''wherever found in captivity'' separately met the definition of a threatened species based on the five factors found in section 4(a)(1) of the Act. Instead, the rule discussed estimated numbers of animals in captivity and known captive-breeding programs, stating in response to a comment that some chimpanzee breeding groups were being managed in the United States with the objective of achieving self-sustainability. The five-factor analysis in both the proposed and final listing rules considered only information applicable to wild populations and within the taxanomic species' native range.

Section 4: Delisting Captive-Held Specimens

If wild populations and groups of captive-held specimens could qualify as separate listable entities, and because groupings of captive-held specimens may not meet the definitions of endangered or threatened under the statutory factors (as discussed above), captive-held specimens currently listed as endangered or threatened (because they were originally listed along with wild specimens as a single listed entity) could be petitioned for, and might qualify for, delisting. These specimens would therefore lose any legal protections of the Act, even as wild populations continue to decline, including to the point of extirpation in the wild. This likewise would not be consistent with the purpose of the Act.

Section 4: Listing Effects on Wild Populations

If wild specimen populations and groups of captive-held specimens could qualify as separate listable entities, and because the analysis for determining legal status of wild populations would be separate from the analysis for determining legal status of captive specimens, the wild population would likely qualify for delisting in the event that all specimens are lost from the wild (in other words, if they became extinct in the wild), thereby removing both incentives and protections for conservation of the species in the wild and the conservation of its ecosystem.

Under the Service's standard section 4 process, both captive-held and wild specimens of the species are members of the listed entity and have legal status as endangered or threatened. In situations where all specimens in the wild are gone, either because they are extirpated due to threats or because, as a last conservation resort, the remaining wild specimens are captured and moved into captivity, the species remains listed until specimens from captivity can be reintroduced to the wild and wild populations are recovered. However, if captive specimens and wild populations could have separate legal status, once all members of the wild population were gone from the wild, the wild population could be petitioned for and would likely qualify for delisting under 50 CFR 424.11(d)(1) as a ''species'' that is now extinct. As shown above, the separate captive-held members of the taxonomic species might not qualify for legal status as endangered or threatened, due to the lack of ''threats'' that create a risk of extinction to the viability of a sustainable, well-managed pool of captive animals. With no listed entities and therefore no authority to use funding or other provisions of the Act for the species, the Service would lose valuable tools for recovery of the species to the wild. This would clearly not be consistent with the purpose of the Act.

Section 7: Consultation

All Federal agencies have a legal obligation to ensure that their actions are not likely to jeopardize the continued existence of endangered and threatened species. This means that for separately listed captive-held endangered or threatened specimens, any Federal agency that is taking an action within the United States or on the high seas that may affect the captive-held listed species arguably would have a legal duty to consult with the Service. However, the section 7 consultation process is not well suited to analysis of adverse impacts posed to a purely captive-held group of specimens given that such specimens are maintained under controlled, artificial conditions.

Section 4: Designation of Critical Habitat

For any listed entity located within the United States or on the high seas, we have a section 4 duty to designate critical habitat unless such habitat is not prudent.[9] Although it is appropriate not to designate critical habitat for foreign species or to limit a critical habitat designation to natural habitats for U.S. species when a listing is focused on the species in the wild (even when some members of the species may be held in captivity within the United States), it is not clear how the Service would support not designating critical habitat when the listed entity would consist entirely of captive-held specimens (when the focus of captivity is within the United States). As with the consultation process, the critical habitat designation duty is not well suited for listings that consist entirely of captive-held specimens, especially given the anomaly of identifying the physical and biological features that would be essential to the conservation of a species

[9] Making a not determinable finding is also an option under section 4(b)(6) of the statute, but only delays the requirement to designate such critical habitat.

consisting entirely of captive animals in an artificial environment. These complexities related to section 7 consultations and designation of critical habitat indicate that Congress did not intend the Service to treat groups of captive-held specimens as separate listable entities on the basis of their captive state.

Legislative History

Legislative history surrounding the 1978 amendment of the definition of ''species'' in the Act indicates that Congress intended designation of a DPS to be used for wild vertebrate populations, not separation of captive-held specimens from wild members of the same taxonomic species. The original (1973) definition of species was ''any subspecies . . . and any other group of fish or wildlife of the same species or smaller taxa in common spatial arrangement that interbreed when mature'' (Pub. L. 93–205). In 1978, Congress amended the Act to the Act's current definition of species, substituting ''distinct population segment'' for ''any other group'' and ''common spatial distribution'' following testimony on the inadequacy of the original definition, such as the exclusion of one category of populations commonly recognized by biologists: disjunct allopatric populations that are separated by *geographic barriers* from other populations of the same species and are consequently reproductively isolated from them physically (See Endangered Species Act Oversight: Hearing Before Senate Subcommittee on Resource Protection, Senate Committee on Environment and Public Works, 95th Cong. 50 (July 7, 1977) (here after 1977 Oversight Hearing) (letter from Tom Cade, Program Director, The Peregrine Fund, to Director of the Service). Although there was discussion regarding population stocks and reproductive isolation generally, particularly in association with development of the 1973 definition,[10] discussions that provide additional context on the scope of the definition of ''species'' show that Congress thought of the population-based listing authority as appropriate for populations that are distinct for natural and evolutionary reasons. For example, one witness discussed ''species'' as associated with the concept of geographic reproductive isolation and including characteristics of a population's ability or inability to freely exchange genes *in nature* (See 1977 Oversight Hearing at 50 (Cade letter)). There is no evidence that Congress intended for the agency to use the authority to separately list groups of animals that have been artificially separated from other members of the species through human removal from the wild and maintenance in a controlled environment. Examples in testimony for which population-based listing authority would be appropriately used were all for wild populations (See 1973 Hearing on H.R. 37 and others at 307 (statement of Stephen Seater, Defenders of Wildlife); Endangered Species Act of 1973: Hearings on S. 1592 and S. 1983 Before the Senate Subcomm. on Environment, Senate Comm. on Commerce, 93d Cong. 98 (1973) (statement of John Grandy, National Parks and Conservation Assoc.); Endangered Species Authorization: Hearings on H.R. 10883 Before the House Subcomm. on Fisheries and Wildlife Conservation and the Environment, House Comm. on Merchant Marine and Fisheries, 95th Cong. 560 (1978) (statement of Michael Bean, Environmental Defense Fund)). No examples were given suggesting designation of captive-held vertebrates as a DPS.

Other Potential Approaches for Separate Legal Status

In addition to separate designation as ''species,'' there are two other approaches under which it could be argued that captive-held specimens could be given separate legal status from their wild counterparts: (1) Simply excluding captive-held members of the taxonomic species, subspecies, or DPS from the Act's protections, or (2) designating only wild members of the taxonomic species as a DPS, with captive-held specimens not included in the DPS. However, neither approach would be consistent with Congress' intent for the Act.

One court already determined that captive-held specimens of a listable entity cannot simply be excluded when they are members of the listable entity and the Service agrees with the court's reasoning in this case. The Service cannot exclude captive-held animals from a listing once these animals are determined to be part of the species. This case—*Alsea Valley Alliance* v. *Evans*—involved the listing of coho salmon by the NMFS. NMFS's 1993 Hatchery Policy (58 FR 17573; April 5, 1993) stated that hatchery populations could be included in the listing of wild members of the same evolutionary significant unit (equivalent to a DPS), but only if the hatchery fish were ''essential to recovery.'' In 1998, NMFS listed only ''naturally spawned'' specimens when it listed an evolutionary significant unit (ESU) of coho salmon (63 FR 42587; August 10, 1998). This decision was challenged in court, and the Court found NMFS's listing decision invalid because it excluded hatchery populations (which are fish held in captivity) even though they were part of the same DPS (or ESU) *Alsea Valley Alliance* v. *Evans,* 161 F. Supp. 2d 1154 (D. Or. 2001). The Court held that ''Congress expressly limited the Secretary's ability to make listing distinctions below that of subspecies or a DPS of a species,'' which was the practical result of excluding all hatchery specimens. NMFS subsequently changed its Hatchery Policy in 2005, stating that all hatchery fish that qualify as members of the ESU would be considered part of the ESU, would be considered in determining whether the ESU should be listed as endangered or threatened, and would be included in any listing under the Act (70 FR 37204; June 28, 2005). NMFS's 2005 Hatchery Policy was upheld by the Ninth Circuit Court in *Trout Unlimited* v. *Lohn,* 559 F. 3d 946 (2009).

For the same reasons as discussed earlier in this document, the Service also cannot simply designate wild members of the taxonomic species as a DPS, leaving all captive-held animals unlisted. Although this would avoid designating captive-held animals as a separate DPS and would not technically be excluding animals that otherwise have been found to be members of a DPS (and thereby avoid the error the court found in the *Alsea Valley Alliance* v. *Evans* decision), the result would be separate legal status and no legal protections for captive-held specimens, and many of the same legal and conservation consequences discussed above would occur. For these reasons, we also find this outcome to be inconsistent with Congress' intent for the Act, primarily as inconsistent with the purposes of the Act.

Now that we have determined that all chimpanzees, including captive and wild animals, should be considered as a single listable entity under the Act, we will next assess the status of the species and determine if the species meets the definition of endangered or threatened under the Act. In 1990, we determined that chimpanzees in the wild are endangered. This analysis considers new information in light of that previous determination and includes the extent to which captive-held chimpanzees create or contribute to threats to the species or remove or reduce threats to the species by

[10] *See* 1973 Hearing on H.R. 37 and others p. 286 (statement of John Grandy, National Parks and Conservation Assoc.) p. 307 (statement of Stephen Seater, Defenders of Wildlife), and pp. 299–300 (statement of Tom Garrett, Friends of the Earth).

contributing to the conservation of the species.

Species Information

Taxonomy and Species Description

In 1990, when the wild populations of chimpanzees were reclassified to endangered, only three subspecies were recognized. Since that time, the correct taxonomic labeling for chimpanzees has been debated and includes the use of a two-subspecies system, a four-subspecies system, and the use of the species level without subspecific designations (Carlsen *et al.* 2012, p. 5; Morgan *et al.* 2011, p. 7; Plumptre *et al.* 2010, p. 2; Ghobrial *et al.* 2010, p. 2; Oates *et al.* 2008, unpaginated). Today, four subspecies are commonly recognized and include the Central African chimpanzee (*Pan troglodytes troglodytes*), East African chimpanzee (*P. t. schweinfurthii*), West African chimpanzee (*P. t. verus*), and Nigeria–Cameroon chimpanzee (*P. t. ellioti*) (Morgan *et al.* 2011, p. 7; Oates *et al.* 2008, unpaginated).

Characteristics of the chimpanzee include an opposable thumb and prominent mouth. The skin on a chimpanzee's face, ears, palms, and soles of the feet are bare, whereas the rest of the body is covered with brown to black hair. Arms extend beyond the knees. This species walks ''on all four'' but are able to walk on just their legs for more than a kilometer (0.6 miles (mi)) (WWF n.d., unpaginated). The male stands over 1.2 meters (m) (4 feet (ft)) tall and weighs 59 kilograms (kg) (130 pounds (lb)); the female is closer to 0.9 m (3 ft) tall and weighs under 45 kg (100 lb) (AZA 2000, p. 1).

Chimpanzees live in social communities that range from 5 to 150 individuals (Oates *et al.* 2008, unpaginated). A male dominance hierarchy forms the core of the community. Males work together to defend a home range and will occasionally attack and kill individuals from another community (Lonsdorf 2007, pp. 72, 74). These communities do not move around in a group like gorillas or monkeys, but rather spend most of their time in subgroups called parties (Pusey *et al.* 2007, p. 626; Plumptre *et al.* 2003, p. 9). Members of a community may join, or leave, at any time and parties may change frequently in size and composition depending on presence of receptive females, food availability, and activity of the party (Lonsdorf 2007, p. 72; Lehmann and Boesch 2004, p. 207; Humle 2003, p. 17; Plumptre *et al.* 2003, p. 9).

Males remain in the community in which they were born; however, once females become sexually mature, between the ages of 9 and 13, they leave the community to join a new one (Humle 2003, p. 16). Chimpanzees are slow breeders; females do not give birth until they are 12 years of age or older and only have one infant every five or six years. Infants are weaned around four years old, and stay with their mothers until they are about eight to ten years old (Lonsdorf 2007, p. 72; Kormos 2003, p. 1; Plumptre *et al.* 2003, pp. 8, 10, 13). The relationship between the mother and her offspring is critical; young may not survive being orphaned, even after they are weaned (Lonsdorf 2007, p. 72).

Essential Needs of the Species

The chimpanzee lives in a variety of moist and dry forest habitats including savanna woodlands, mosaic grassland forests, and tropical moist forests (Oates *et al.* 2008, unpaginated; Pusey *et al.* 2007, p. 626; GRASP 2005a, p. 6; Butynski 2003, p. 6). In general, chimpanzees need large areas to provide sufficient resources for feeding, nesting, and shelter (Carter 2003b, p. 158). However, home ranges may vary depending on the quality of habitat and community size; competition for food and predation risk may also play a role. Home ranges average 12.5 km^2 (8 mi^2), but can range from 5–400 km^2 (3–249 mi^2) (Oates *et al.* 2008, unpaginated; Humle 2003, pp. 17–18).

Chimpanzees are omnivores; half their diet is ripe fruit, but they also feed on leaves, bark, stems, insects, and mammals, including red colobus (*Procolobus spp.*), black-and-white colobus (*Colobus guereza*) and red-tailed guenons (*Cephalophus monticola*). Diets vary seasonally and between populations, depending on food availability and habitat type (Oates *et al.* 2008, unpaginated; Pusey *et al.* 2007, p. 626; Humle 2003, pp. 13–14; Watts and Mitani 2002, p. 7).

Chimpanzees build arboreal nests in which they sleep at night and may rest during the day (Plumptre *et al.* 2003, p. 10; Humle 2003, p. 15). Nests are constructed by preparing a foundation of solid side branches, bending, breaking, and interweaving side branches crosswise, then bending smaller twigs in a circle around the rim. Chimpanzees exhibit strong preferences for certain tree species for nesting, independent of their availability in the habitat. Choice of nesting sites is variable across populations and communities of chimpanzees and is dependent on habitat structure, resource distribution, predation levels, and human disturbance. Chimps can be deterred from nesting in certain areas where human habitation is concentrated. As a result, human presence influences nesting behavior and can put chimpanzees at risk of predators, since habitats where they relocate nests to avoid humans may not provide sufficient protection (Humle 2003, pp. 15–16).

Range and Population

Historically, this species may have spanned most of Equatorial Africa, from Senegal to southwest Tanzania, ranging over 25 countries (Butynski 2003, p. 6). Today, the chimpanzee has been lost from Benin, Togo, and Burkina Faso. The species now occurs in a wide but discontinuous distribution over 22 countries in an area approximately 2,342,000 square kilometers (km^2) (904,000 square miles (mi^2)) (Carlsen *et al.* 2012, p. 5; Oates *et al.* 2008, unpaginated; Kormos and Boesch 2003, p. 1; Butynski 2003, p. 6).

Chimpanzees are thought to have numbered in the millions at the beginning of the 20th Century, although there are no hard data to support this. Chimpanzee populations are believed to have declined by 66 percent, from 600,000 to 200,000 individuals before the 1980s (Kormos and Boesch 2003, p. 1). Since the 1980s, estimates for the chimpanzee have varied, but in general have increased over the past three decades (See Table 1) (Oates 2006, pp. 102–104; Butynski 2003, p. 10). Using the latest population estimates for each subspecies, the chimpanzee, today, totals between 294,800 and 431,100 individuals; although we note that this estimate does not factor in a recent 90 percent decline in the chimpanzee population of Côte d'Ivoire (see below). The range countries and most recent population estimates for each subspecies are outlined in Table 2.

Table 1. Historical population estimates for chimpanzee.

Year	Estimated Population	Source
1900	1,000,000	Teleki in Butynski 2003, p. 10; Oates 2006, p. 104
1900	2,000,000	Goodall 2000 in Butynski 2003, p. 10
1960	> 1,000,000	Goodall 2000 in Butynski 2003, p. 10
1979	20,000-200,000	Lee *et al*. 1988 in Oates 2006, p. 103
1987	151,000-235,000	Teleki 1989 in Butynski 2003, p. 10; Oates 2006, p. 104
1989	≤ 150,000	Goodall 2000 in Butynski 2003, p. 10
1989	145,000-228,000	Teleki 1991 in Butynski 2003, p. 10
2000	152,200-254,600	Butynski 2001 in Oates 2006, p. 104
2003	173,000-300,000	Butynski 2003, p. 10

Table 2. Range countries and populations estimates for each chimpanzee subspecies.

Subspecies	Range Countries	Population Estimate	Reference
Eastern (*P.t. schweinfurthii*)	Burundi, Central African Republic, Democratic Republic of Congo, Rwanda, Sudan, Tanzania, Uganda	**200,000-250,000**	Plumptre *et al*. 2010, p. 22
Nigeria-Cameroon (*P.t. ellioti*)	Cameroon, Nigeria	**3,500-9,000**	Morgan *et al*. 2011, p. 4
Central (*P.t. troglodytes*)	Angola, Cameroon, Central African Republic, Congo, The Democratic Republic of Congo, Equatorial Guinea, Gabon	**70,000-116,500**	Butynski 2003, p. 8
Western (*P.t. verus*)	Burikina Faso, Côte d'Ivoire, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Nigeria, Senegal, Sierra Leone	**21,300-55,600**	Kormos and Boesch 2003, p. 3; Butynski 2003, p. 8
Total		**294,800-431,100**	

The increase in the chimpanzee population estimates is believed to be a result of the difficulty in producing accurate estimates and the availability of new information, rather than an actual increase in chimpanzee numbers (Oates 2006, p. 104). Accurate data is lacking for most of the chimpanzee populations. Few areas have been adequately surveyed; some chimpanzee populations survive at densities too low for accurate detection; survey methods lack precision to enable extrapolation to large areas of potential habitat; some surveys are outdated; and in many cases estimates are simply best guesses (Morgan *et al.* 2011, p. 9; Plumptre *et al.* 2010, pp. 5, 7, 9, 31, 41; Campbell *et al.* 2008, p. 904; Oates 2006, p. 102; Tutin *et al.* 2005, p. 6; GRASP 2005a, p. 7; Butynski 2003, p. 5; Kormos and Bakarr 2003, p. 29;).

Despite the appearance of an increase in chimpanzee numbers, experts agree that chimpanzee populations are declining (Plumptre *et al.* 2010, p. 1; Greengrass 2009, pp. 77, 80–82; Kabasawa 2009, p. 37; Campbell *et al.* 2008, pp. 903–904; Oates *et al.* 2008, unpaginated; Oates 2006, p. 110; Tutin 2005, p. 2; GRASP 2005a, p. 3; Kormos and Boesch 2003, p. 2; Butynski 2003, p. 11; Nishida *et al.* 2001, pp. 45–46). Data to support a declining trend comes from nationwide surveys of Gabon, Côte d'Ivoire, and Tanzania, data from long-term chimpanzee research sites, a questionnaire survey of great ape field researchers, and the expansion and increasing intensity of threats (Junker *et al.* 2012, p. 3; Plumptre *et al.* 2010, p. 8; Oates 2006, pp. 105–106; Nishida *et al.* 2001, p. 45; Campbell *et al.* 2008, pp. 903–904; Tutin *et al.* 2005, p. 32). One of the greatest documented losses of chimpanzees comes from a 2007 survey of Côte d'Ivoire which found a 90 percent decline in chimpanzees since the last survey conducted in 1989–1990, indicating a significant loss of chimpanzees from a country once thought to be one of the final strongholds of the western chimpanzee (Campbell *et al.* 2008, p. 903). Many remaining populations are now small, isolated, and face serious threats (Oates 2006, pp. 104, 110). Furthermore, the chimpanzee has already been extirpated from three countries. Due to the high risk of extinction for populations under 600 individuals (Oates 2006, p. 108), the chimpanzee could be extirpated from an additional four countries: Nigeria, Senegal, Ghana, and Guinea–Bissau (Carlsen *et al.* 2012, p. 5; Butynski 2003, p. 11; Kormos and Boesch 2003, p. 3).

In addition to wild populations, chimpanzees are held in captivity in several countries around the world, including African countries and the United States. We do not have detailed information on the number, subspecies, or the location of captive chimpanzees. However, we did find information indicating that 70 chimpanzees are

living in sanctuaries in Cameroon and Nigeria (Morgan *et al.* 2011, p. 9). Approximately 171 chimpanzees are living in sanctuaries throughout West Africa; another 478 chimpanzees in the region are known to be held outside of sanctuaries (e.g., homes or hotels) (Kormos and Boesch 2003, p. 4). Within the United States, approximately 2,000 chimpanzees are in captivity (ChimpCare 2013, unpaginated; Ross *et al.* 2008, p. 1,487).

Summary of Threats

Threats to the chimpanzee have intensified and expanded since 1990, when wild populations of the chimpanzee were listed as endangered. Across its range, high deforestation rates are destroying, degrading, and fragmenting forests the chimpanzee needs to support viable populations and provide food and shelter. Widespread poaching, capture for the pet trade, and outbreaks of disease are removing individuals needed to sustain viable populations; recovery from the loss of individuals is more difficult given the slow reproductive rates of chimpanzees. These actions are exacerbated by an increasing human population, the expansion of settlements, and increasing pressure on natural resources to meet the needs of the growing population (Morgan *et al.* 2011, p. 10; Plumptre *et al.* 2010, p. 2; Kabasawa 2009, p. 37; Campbell *et al.* 2008, p. 903; Lonsdorf 2007, p. 72; Unti 2007a, p. 4; Unti 2007b, p. 5; Bennett 2006, p. 885; Tutin *et al.* 2005, p. 1; GRASP 2005a, p. 3; Kormos 2003, pp. ix, 1; Kormos and Boesch 2003, p. 4; Nisbett *et al.* 2003, p. 97; Walsh *et al.* 2003, pp. 611–612; Carter *et al.* 2003, p. 38).

Deforestation, with consequent access and disturbance by humans, remains a major factor in the decline of chimpanzee populations across their range. Although some large forest blocks remain, commercial logging and the conversion of forests to agricultural land continue to severely reduce and fragment chimpanzee habitat (Morgan *et al.* 2011, pp. 12, 18, 19, 26, 31; Plumptre *et al.* 2010, p. 2; Oates *et al.* 2008, unpaginated; Unti 2007a, p. 4; Unti 2007b, p. 5; CBFP 2006, p. 16; Fa *et al.* 2006, p. 498; Tutin *et al.* 2005, pp. 1, 2, 10, 12, 14–17, 21–23; Humle 2003, p. 150; Carter *et al.* 2003, p. 38; Duvall *et al.* 2003, p. 47; Gippoliti *et al.* 2003, p. 57; Hanson-Alp *et al.* 2003, p. 83; Herbinger *et al.* 2003, pp. 106, 109; Kormos *et al.* 2003b, p. 71; Kormos *et al.* 2003c, p. 151; Magnuson *et al.* 2003, p. 113; Nisbett *et al.* 2003, pp. 95, 97; Oates *et al.* 2003, p. 129; Walsh *et al.* 2003, p. 613; Parren and Byler 2003, p. 135). As the human population and economic development have increased, pressure on forest resources has also increased. This increasing pressure has led to uncontrolled legal and illegal forest conversion within and outside of protected areas (e.g., national parks and forest reserves), leaving them destroyed and fragmented (Greengrass 2009, pp. 77, 80; Campbell *et al.* 2008, p. 903; CBFP 2006, pp. 16, 33; Nasi *et al.* 2006, p. 14; Carter *et al.* 2003, p. 38; Duvall *et al.* 2003, p. 47; Herbinger *et al.* 2003, p. 109; Magnuson *et al.* 2003, p. 113; Oates *et al.* 2003, p. 129; Parren and Byler 2003, pp. 135, 137).

The natural protection once afforded to chimpanzees by large blocks of suitable habitat, isolated from human activities, is disappearing due to logging activity. Much of the chimpanzee's range is already allocated to logging concessions, and logging operations, both legal and illegal, are expanding (Morgan *et al.* 2011, pp. 12, 26; Laporte *et al.* 2007, p. 1451; Morgan and Sanz 2007, pp. 3, 5; CBFP 2006, p. 29; Hewitt 2006, p. 43; Nasi *et al.* 2006, p. 14; Tutin 2005, pp. 2, 4, 12, 30, 32; Kormos *et al.* 2003a, p. 29). Heavy pressures on timber resources have led to cutting cycles that occur too frequently in an area to allow for proper regrowth, resulting in rapid degradation of forests (Parren and Byler 2003, p. 135). In addition to clearing forests, logging operations often create a network of roads for transporting timber. These roads provide greater access to forests that were once inaccessible, facilitate the establishment of human settlements, and are accompanied by further deforestation from the conversion of forests to agriculture (Junker *et al.* 2012, p. 7; Morgan *et al.,* 2011, p. 12; Plumptre *et al.* 2010, p. 2; Greengrass 2009, p. 80; Laporte *et al.* 2007, p. 1451; Hewitt 2006, p. 44; Duvall 2003, p. 143; Oates *et al.* 2003, p. 129; Parren and Byler 2003, pp. 133, 137–138).

Human population growth and agricultural expansion have destroyed and fragmented forests across the range of the chimpanzee and are two of the greatest threats to chimpanzee survival. Plantations and farms have been established in suitable chimpanzee habitat, including within protected areas (Plumptre *et al.* 2010, p. 9; Greengrass 2009, p. 80; Unti 2007a, p. 4; Unti 2007b, p. 5; Tutin *et al.* 2005, p. 20; Duvall 2003, p. 143; Gippoliti *et al.* 2003, pp. 55, 57; Hanson-Alp *et al.* 2003, p. 83; Humle 2003, p. 147; Kormos *et al.* 2003b, p. 63; Magnuson *et* al. 2003, p. 113; Parren and Byler 2003, p. 138). In West Africa, most unreserved forests have been converted to cultivation (Parren and Byler 2003, p. 138). Agricultural practices are largely unsustainable and are encroaching into additional forested areas (Parren and Byler 2003, p. 133).

Chimpanzees are highly adaptive and occur in a variety of habitats, including primary, secondary, and regenerating forests, logged forests, and plantations; they have even been found living in close proximity to humans. However, the loss, or even the degradation, of the chimpanzee's traditional habitat can affect their survival by impacting its food resources, behavior, susceptibility to disease, and abundance and distribution, (Morgan and Sanz 2007, p. 1; Carter *et al.* 2003, p. 36; Hanson-Alp *et al.* 2003, p. 83; Kormos and Boesch 2003, p. 18; Nisbett *et al.* 2003, p. 97; Parren and Byler 2003, p. 137).

Although chimpanzees feed on a wide variety of foods, their energy requirements, as large primates with large home ranges, predispose them to a reliance on high-energy fruits (Greengrass 2009, p. 81). Removal, or lowering the quality, of habitat through logging activity or establishment of agricultural lands destroys the structure and composition of the forest, eliminating essential food sources, which can affect sociability, condition of individuals, and female reproductive success, and increase vulnerability to diseases or parasites and infant and juvenile mortality (Greengrass 2009, pp. 81–82). Even in areas with lower levels of logging where essential food sources were unaffected, chimpanzee densities have declined significantly and remained low for years. Clear-cutting results in total habitat loss, and because of severe soil erosion, the potential for future forest regeneration is also lost (Parren and Byler 2003, pp. 137–138).

The loss or reduction of food sources and the noise and disturbance from logging activity can cause chimpanzee communities to abandon their home range to find a new home range with sufficient resources and less human activity. These chimpanzees may enter another community's territory which can lead to further competition for resources and conflict that can lead to death. As habitat is lost or fragmented and chimpanzee populations are forced into smaller forest fragments, lethal interactions with other chimpanzees may increase. Furthermore, chimpanzees may be cautious about reinhabiting previous home ranges where they were displaced by humans (Morgan *et al.* 2011, p. 12; Lonsdorf 2007, p. 74; Carter *et al.* 2003, p. 36; Parren and Byler 2003, pp. 137–138). If the displacement of chimpanzees forces them into suboptimal habitat, they may not have sufficient protection from

predators, especially at night (Humle 2003, pp. 15–16).

The loss or reduction of food sources due to expanding logging, agriculture, and human settlements into chimpanzee habitat has also resulted in increased conflicts between humans and chimpanzees (Tacugama Sanctuary 2013, unpaginated; Unti 2007b, p. 5; Tweheyo *et al.* 2005, pp. 237–238, 244; Herbinger *et al.* 2003, p. 106; Humle 2003, p. 147; Kormos *et al.* 2003b, p. 71; Naughton-Treves *et al.* 1998, pp. 597, 600). Lack of sufficient wild food and an increase in farming and human presence have increased the occurrence of crop raiding to supplement their diet. Crop raiding can cause substantial losses to farmers, reduce the tolerance of humans to chimpanzee presence, and increase killing chimpanzees to protect valuable crops or in retaliation for the destruction of crops (Tacugama Chimpanzee Sanctuary 2013, unpaginated; Oates *et al.* 2008, unpaginated; Bennett *et al.* 2006, p. 885; Tweheyo *et al.* 2005, p. 245; Duvall 2003, p. 144; Carter *et al.* 2003, p. 36; Gippoliti *et al.* 2003, p. 57; Humle 2003, pp. 147, 150; Parren and Byler 2003, p. 138; Naughton-Treves 1998, p. 597).

Unsustainable hunting for the bushmeat trade is one of the major causes of the decline in chimpanzees, and continues to be a major threat to the survival of chimpanzees in protected and unprotected areas (Ghobrial *et al.* 2011, pp. 1, 2, 11; Morgan *et al.* 2011, p. 10; Hicks *et al.* 2010, pp. 1, 3, 6, 11; Plumptre *et al.* 2010, p. 2; Kabasawa 2009, p. 37; Campbell *et al.* 2008, p. 903; Oates *et al.* 2008, unpaginated; Lonsdorf 2007, p. 74; Unti 2007b, p. 5; Tutin *et al.* 2005, pp. 1, 10–23, 27–28; Herbinger *et al.* 2003, p. 109; Humle 2003, p. 17; Kormos and Boesch 2003, pp. 2, 14, 16, 19; Kormos *et al.* 2003b, p. 63; Kormos *et al.* 2003c, p. 151; Magnuson *et al.* 2003, pp. 111, 113; Nisbett *et al.* 2003, p. 95; Oates *et al.* 2003, pp. 123, 129; Nishida *et al.* 2001, p. 47; Bowen-Jones 1998, p. 12). Growth in the human population in Africa has increased the demand for wild animal meat, or bushmeat. Expansion of logging activities, including the construction of logging roads, has facilitated a significant market, much of it illegal, for commercial bushmeat to meet this demand (Amati *et al.* 2009, p. 6; Kabasawa 2009, pp. 50–51; AV Oates *et al.* 2008, unpaginated; Fa *et al.* 2006, pp. 503, 506; Magazine 2003, p. 7; Kormos *et al.* 2003c, p. 151; Walsh *et al.* 2003, p. 613; Nishida *et al.* 2001, p. 47; Bowen-Jones 1998, pp. 1, 11). Logging roads and vehicles provide access to the forests and a means to export meat to markets and cities. Logging operations are accompanied by an onslaught of workers who are encouraged to hunt to provide for their own needs and commercial hunters who operate in forests to supply the needs of forestry workers and to trade outside of the forested areas (Plumptre *et al.* 2010, p. 2; Kormos *et al.* 2003c, p. 151; Nisbett *et* al. 2003, p. 95; Walsh *et al.* 2003, p. 613; Nishida *et al.* 2001, p. 47; Bowen-Jones 1998, p. 1). Furthermore, bushmeat trade is also an important livelihood and the primary source of protein for humans in much of the chimpanzee's range (Abwe and Morgan 2008, p. 26; Fa *et al.* 2006, p. 507; Bennett *et al.* 2006, p. 885; Kormos *et al.* 2003c, p. 155; Wilkie and Carpenter 1999, p. 927).

The intensity of hunting chimpanzees varies by country and region (Kormos *et al.* 2003c, pp. 151–152). Religious, traditional, and familial taboos against the killing of chimpanzees and the consumption of their meat exist in many areas (Hicks *et al.* 2010, p. 9; Plumptre *et al.* 2010, p. 2; Greengrass 2009, p. 81; Kabasawa 2009, p. 51; Unti 2007a, p. 4; Carter *et al.* 2003, pp. 31, 38; Duvall *et al.* 2003, p. 47; Gippoliti *et al.* 2003, pp. 55, 57; Humle 2003, p. 18; Kormos and Boesch 2003, pp. 10, 13; Kormos *et al.* 2003b, pp. 63, 71; Kormos *et al.* 2003c, pp. 152, 154; Nisbett *et* al. 2003, p. 95; Oates *et al.* 2003, p. 129; Waller and Reynolds 2001, p. 135; Bowen-Jones 1998, pp. 19, 27). However, these areas may be hunted by people from surrounding areas where there is demand for chimpanzee meat (Kormos *et al.* 2003b, p. 72). Furthermore, these traditions and beliefs are not necessarily being passed down to younger generations and cannot be relied on to protect chimpanzees in the future (Hicks *et al.* 2010, p. 9; Unti 2007a, p. 4; Oates *et al.* 2003, p. 129).

Despite the high demand for bushmeat, primates do not represent the majority of animals killed for the bushmeat trade (AV Magazine 2003, p. 7; Magnuson *et al.* 2003, p. 113; Walsh *et al.* 2003, p. 613; Nishida *et al.* 2001, p. 47; Bowen-Jones 1998, p. 1). In fact, studies have found that chimpanzee meat makes up only a small fraction of the meat found in markets; estimates from different regions have ranged from 0.01 to 3 percent (Kabasawa 2009, p. 38; Fa *et al.* 2006, p. 502; Herbinger *et al.* 2003, p. 106; Kormos and Boesch 2003, p. 2; Kormos *et al.* 2003c, pp. 151–152). However, because the sale of ape meat is often hidden and the meat may be eaten in villages and never make it to markets, the proportion of chimpanzee meat in bushmeat markets could be greater than reported (Kabasawa 2009, p. 38; Kormos *et al.* 2003c, pp. 151–152; Bowen-Jones 1998, pp. 21–11). Hunting pressure even at a low level is enough to result in the local extirpation of large chimpanzee populations. Low population densities and slow reproductive rates prevent chimpanzees from recovering easily from the loss of several individuals (Oates *et al.* 2008, unpaginated; Fa *et al.* 2006, p. 503; AV Magazine 2003, p. 7; Duvall *et al.* 2003, p. 47; Herbinger *et al.* 2003, p. 106; Kormos and Boesch 2003, p. 2; Kormos *et al.* 2003c, pp. 151, 153; Nisbett *et al.* 2003, p. 95; Magnuson *et al.* 2003, p. 113; Bowen-Jones 1998, p. 13).

Threats to the chimpanzee from habitat loss and commercial hunting have been exacerbated by civil unrest that has occurred in several chimpanzee range countries (Plumptre *et al.* 2010, pp. 4–5; Campbell *et al.* 2008, p. 903; CBFP 2006, p. 16; Hanson-Alp *et al.* 2003, p. 85; Nisbett *et al.* 2003, pp. 89, 95; Draulans and Van Krunkelsven 2002, pp. 35–36). During civil conflict, many people, including refugees, military groups, and rebels take shelter in interior forests and protected areas (Plumptre *et al.* 2010, p. 4; CBFP 2006, p. 16). The presence of soldiers and displaced refugees increases the number of people that rely on bushmeat for protein. Not only do soldiers hunt, but they also supply locals with weapons and ammunition to hunt them (Plumptre *et al.* 2010, p. 5; Hanson-Alp *et al.* 2003, p. 85; Draulans and Van Krunkelsven 2002, pp. 35–36;). Civil unrest has contributed to a significant loss of wildlife, including chimpanzees (Campbell *et al.* 2008, p. 903; Hanson-Alp *et al.* 2003, p. 85).

Capture of live chimpanzees for the international pet trade has been one of the major causes of the decline in chimpanzees. Today, illegal capture and smuggling of chimpanzees continue for the pet trade across Africa and, to some extent, the international market (Ghobrial *et al.* 2010, pp. 1, 2, 11; Kabasawa 2009, pp. 37, 48–49; Oates *et al.* 2008, unpaginated; Carter 2003b, p. 157; Kormos and Boesch 2003, p. 4; Nisbett *et al.* 2003, p. 95). A recent increase in orphaned chimpanzees has been attributed to the growing bushmeat crisis. Killing a mother with an infant earns twice the income for the hunter; the mother's body is sold in the bushmeat trade while the infant enters the pet trade (Kabasawa 2009, p. 50; Carter 2003b, p. 157). Furthermore, hunters have found a lucrative market for pet chimpanzees with military personnel, police, government officials, and traditional chiefs (Hicks *et al.* 2010, p. 8; Draulans and Van Krunkelsven 2002, pp. 35–36). The intensity of trade differs among countries, but is

reportedly a substantial problem in The Democratic Republic of the Congo, Côte d'Ivoire, Sierra Leone, Ghana, and Guinea (Hicks *et al.* 2010, pp. 3, 6, 11; Plumptre *et al.* 2010, p. 2; Unit 2007, p. 5; Unti 2007a, p. 4; Hanson-Alp *et al.* 2003, p. 84; Herbinger *et al.* 2003, p. 106; Kormos *et al.* 2003b, p. 72; Magnuson *et al.* 2003, p. 113). It is not possible to determine how many wild chimpanzees are captured for the pet trade, but the number of chimpanzees in sanctuaries indicates it is a significant problem. Since 2000, the number of chimpanzees in African sanctuaries has increased 59 percent (Kabasawa 2009, pp. 37, 50).

The petitioners assert that the exploitation of chimpanzees in the United States' entertainment and pet industries is seen around the world and misleads the public into believing chimpanzees are well protected in the wild and make good pets, further fueling the demand for chimpanzees. Studies suggest a link between seeing chimpanzees portrayed in the media and misperceptions about the species' status in the wild. This misperception may also affect conservation efforts (Ross *et al.* 2011, pp. 1, 4–5; Schroepfer *et al.* 2011, pp. 6–7; Ross 2008a, pp. 25–26; Ross *et al.* 2008b, p. 1487). However, we did not find evidence that this situation was a significant driver in the status of the species.

The effects of the pet trade are particularly devastating to wild populations because the mother and other family members may be killed to capture an infant. Researchers estimate that as many as 10 chimpanzees may be killed for every infant that enters the pet trade. Furthermore, the infant is likely to die of malnutrition, disease, or injury (Hicks *et al.* 2010, p. 8; Kabasawa 2009, p. 49; Lonsdorf 2007, p. 74; Carter 2003b, p. 157; Hanson-Alp *et al.* 2003, p. 84; Kormos and Boesch 2003, p. 4). The loss of even just a few individuals from a population can have devastating effects due to the slow reproductive rate of chimpanzees. Because so many chimpanzees may be killed to secure an infant, the pet trade has a significant draining effect on remaining populations, and threatens the survival of wild chimpanzees (Kabasawa 2009, p. 49; Carter 2003b, p. 157; Magnuson *et al.* 2003, p. 113).

Historically, wild chimpanzees were captured and exported to meet a significant demand for chimpanzees in biomedical research in countries around the world, significantly impacting chimpanzee distribution and abundance (Unti 2007a, p. 4; Unti 2007b, p. 5; Kormos *et al.* 2003b, p. 72). A substantial number of countries do not permit or conduct research on chimpanzees and the international research community is no longer seeking access to wild chimpanzees (Hicks 2011, pers. comm.; Unti 2007a, p. 4; Unti 2007b, p. 5). Although some biomedical research on captive chimpanzees continues in the United States and Gabon, in the United States, there is a decreasing scientific need for chimpanzee studies due to the emergence of non-chimpanzee models and technologies (Institute of Medicine 2011, pp. 5, 66–67).

As previously stated, chimpanzees are held in captivity in several countries around the world, including African countries and the United States. Chimpanzees in captivity are bred and sold as pets, used in the entertainment industry (e.g., movies, television, and advertisements), exhibited in hotels and roadside shows, used as party entertainment or animal encounters, displayed in zoos, and used for biomedical research. It is thought that self-sustaining breeding groups of captive chimpanzees provide surplus animals for research and other purposes, thereby reducing the demand for wild individuals. Given that threats to the chimpanzee have expanded and intensified, and capture for the illegal pet trade continues to be a major threat to remaining chimpanzee populations, it does not appear that the availability of captive chimpanzees has reduced any threats to the species.

National laws exist within all range countries to protect chimpanzees. In general, hunting, capture, possession, and commercial trade of chimpanzees are prohibited. Laws also protect chimpanzee habitat, including the establishment of protected areas, in many of the range countries. However, as evidenced by the continuing and increasing habitat destruction and hunting and trading of this species, even within protected areas, these laws are not often enforced. A lack of resources, limited training, limited personnel, lack of basic logistical support, corrupt officials, and weak legislation prevent government agencies charged with the protection of wildlife and forest management from providing effective protection. Furthermore, penalties for violations are not adequate to serve as a deterrent (Ghobrial *et al.* 2010, pp. 1, 2, 11; Hicks *et al.* 2010, pp. 8–9; Kabsawa 2009, p. 39; Laporte *et al.* 2009, p. 1451; Unti 2007a, pp. 4, 6, 8, 10–11; Unti 2007b, pp. 6–10; Bennett *et al.* 2006, p. 885; AV Magazine 2003, p. 7; Carter 2003a, p. 52; Carter 2003b, p. 157; Carter *et al.* 2003, pp. 31, 32, 38; Duvall *et al.* 2003, p. 47; Hanson-Alp *et al.* 2003, p. 79, 87; Herbinger *et al.* 2003, pp. 100, 106; Kormos and Boesch 2003, p. 6; Kormos *et al.* 2003b, p. 64; Kormos *et al.* 2003c, p. 155; Magnuson *et al.* 2003, p. 112; Nisbett *et al.* 2003, pp. 90, 95; Oates *et al.* 2003, pp. 123, 125).

The chimpanzee is also protected under the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), an international agreement between governments to ensure that the international trade of CITES-listed plant and animal species does not threaten species' survival in the wild. Under this treaty, CITES Parties (member countries or signatories) regulate the import, export, and reexport of specimens, parts, and products of CITES-listed plant and animal species. Trade must be authorized through a system of permits and certificates that are provided by the designated CITES Management Authority of each CITES Party. With the exception of Angola, all chimpanzee range countries are Parties to CITES.

The chimpanzee is listed in Appendix I of CITES. An Appendix-I listing includes species threatened with extinction whose trade is permitted only under exceptional circumstances, which generally precludes commercial trade. The import of an Appendix-I species generally requires the issuance of both an import and export permit. Import permits for Appendix-I species are issued only if findings are made that the import would be for purposes that are not detrimental to the survival of the species and that the specimen will not be used for primarily commercial purposes (CITES Article III(3)). Export permits for Appendix-I species are issued only if findings are made that the specimen was legally acquired and trade is not detrimental to the survival of the species, and if the issuing authority is satisfied that an import permit has been granted for the specimen (CITES Article III(2)).

Based on CITES trade data from 1990–2011, obtained from United Nations Environment Programme–World Conservation Monitoring Center (UNEP–WCMC) CITES Trade Database, there has been significant legal trade of chimpanzees and their parts, and products worldwide. However, legal trade in wild specimens, including live animals, bones, scientific specimens, and hair has been limited. Trade of these wild specimens for commercial purposes was reported for 14 live specimens, 121 scientific specimens, and 10 skulls. From 2002–2011, exports and re-exports of wild specimens from the United States have numbered 8 scientific specimens for scientific purposes. Imports of wild specimens into the United States have been limited

and have included hairs, scientific specimens, a skull, and one unspecified specimen for personal, scientific, educational, and medical purposes.

As human settlements expand and populations of chimpanzees and their habitat are reduced, interactions between chimpanzees and humans or human waste increases, leading to greater risks of disease transmission. A close genetic relationship allows for easy transmission of infectious diseases between chimpanzees and humans (Plumptre *et al.* 2010, p. 2; Oates *et al.* 2008, unpaginated; Lonsdorf 2007, p. 73; Tutin *et al.* 2005, p. 29; Formenty *et al.* 2003, p. 169; Huijbregts *et al.* 2003, p. 437). Rural communities that share the same habitat as chimpanzees have no access to health care and are not vaccinated against diseases that can spread through ape populations and result in high mortality rates. Additionally, exposure to humans through conservation and research activities, such as habituation, ecotourism, and reintroductions can also increase the risk of disease transmission (Plumptre *et al.* 2010, p. 2; Köndgen *et al.* 2008, p. 260; Oates *et al.* 2008, unpaginated; Tutin *et al.* 2005, p. 29; Huijbregts *et al.* 2003, p. 437; Nishida *et al.* 2001, p. 48).

Disease transmission is a major threat to remaining populations of the central and eastern chimpanzees (Morgan *et al.* 2011, p. 10; Plumptre *et* al. 2010, p. 2; GRASP 2005a, p. 7; Tutin *et al.* 2005, p. 2; Leendertz *et al.* 2004, p. 451; Walsh *et al.* 2003, p. 612). Repeated epidemics of Ebola virus have resulted in dramatic declines in ape populations in Côte d'Ivoire, Gabon, Democratic Republic of the Congo, and the Republic of Congo (Plumptre *et al.* 2010, p. 2; Köndgen *et al.* 2008, p. 261; Oates *et al.* 2008, unpaginated; Tutin *et al.* 2005, p. 29; Leendertz *et al.* 2004, p. 451; Huijbregts *et al.* 2003, pp. 437, 441; Walsh *et al.* 2003, pp. 612–613; Formenty *et al.* 2003, pp. 169–172). Other infectious diseases have resulted in the death of chimpanzees at Gombe, Mahale, and Taï national parks (Rudicell *et al.* 2010, pp. 1, 10; Oates *et al.* 2008, unpaginated; Köndgen *et al.* 2008, pp. 260–262; Williams *et al.* 2008, pp. 766, 768–770; Leendertz *et al.* 2004, pp. 451–452; Nishida *et al.* 2001, p. 48).

Once a chimpanzee population has been reduced, whether by hunting, capture for the pet trade, or disease, its ability to recover is limited due to very slow reproductive rates and complex social behavior (Plumptre *et al.* 2010, p. 1; Kabasawa 2009, p. 49; Bennett *et al.* 2006, p. 885; Tutin *et al.* 2005, p. 32; Kormos *et al.* 2003c, pp. 151, 155; Wilkie and Carpenter 1999, p. 927;). Even low levels of hunting can have a devastating effect on the population. The loss of reproductive-age female chimpanzees can be particularly devastating, further reducing the population's ability to recover from the loss (Carter 2003b, p. 157; Kormos *et al.* 2003b, p. 72). The occurrence of chimpanzees at low densities coupled with slow reproductive rates can lead to the rapid extinction of even large populations (Oates *et al.* 2008, unpaginated; Kormos and Boesch 2003, p. 2).

The current threats to the chimpanzee, as described above, are not likely to improve in the future, resulting in a continuing decline of chimpanzee populations. Threats to this species are driven by the needs of an expanding human population. Within the range countries of the chimpanzee, the human population is expected to continue to increase and will inevitably increase the pressures on natural resources. Therefore, impacts to remaining populations of chimpanzees, as described above, from deforestation, hunting, commercial trade, and disease are likely to continue or even intensify (Morgan *et al.* 2011, p. 10 Plumptre *et al.* 2010, pp. 50, 71; Fitzherbert *et al.* 2008, pp. 538–539, 544; Oates *et al.* 2008, unpaginated; CBFP 2006, p. 33; Fa *et al.* 2006, p. 506; Hewitt 2006, pp. 44, 48–49; Nasi *et al.* 2006, p. 14; Carter *et al.* 2003, p. 38; Duvall 2003, p. 145; Parren and Byler 2003, p. 137; Nishida *et al.* 2001, p. 45; Wilkie and Carpenter 1999, pp. 927–928).

Continuing threats acting on chimpanzee populations, coupled with the species' inability to recover from population reductions, will likely lead to the loss of additional populations. Chimpanzees could be lost from an additional three countries due to threats acting on populations that fall below what is considered the minimum for a viable population (Carlsen *et al.* 2012, p. 5; Butynski 2003, p. 11; Kormos and Boesch 2003, p. 3). Many remaining populations are small and isolated, putting them at an increased risk of extinction (Morgan *et al.* 2011, p. 12).

Many management plans have been developed to conserve the chimpanzee (e.g., Morgan *et al.* 2011; Plumptre *et al.* 2010; GRASP 2005a; GRASP 2005b; Tutin *et al.* 2005; Kormos and Boesch 2003; Kormos *et al.* 2003). These plans lay out goals and research needs to address the threats faced by chimpanzees. Development of forest management plans with the goal of sustainable forestry practices has increased (Hewitt 2006, p. 43; Nasi *et al.* 2006, pp. 17–19). However, implementation of these management plans faces challenges, and the effect of these plans has yet to be determined. There is no evidence that management plans have reduced threats to the species. Chimpanzees are found in numerous protected areas. In some cases, these areas provide adequate protection and support substantial populations of chimpanzees. Unfortunately, many protected areas have weak or nonexistent management with poor law enforcement and are illegally logged, converted to agricultural lands, and hunted (Campbell *et al.* 2011, p. 1). Furthermore, we have no evidence that enforcement of legislation to protect chimpanzees and their habitat, including protected areas, will improve.

Finding

Section 4 of the Act (16 U.S.C. 1533) and implementing regulations (50 CFR part 424) set forth procedures for adding species to, removing species from, or reclassifying species on the Federal Lists of Endangered and Threatened Wildlife and Plants. Under section 4(a)(1) of the Act, a species may be determined to be endangered or threatened based on any of the following five factors:

(A) The present or threatened destruction, modification, or curtailment of its habitat or range;

(B) Overutilization for commercial, recreational, scientific, or educational purposes;

(C) Disease or predation;

(D) The inadequacy of existing regulatory mechanisms; or

(E) Other natural or manmade factors affecting its continued existence.

In considering whether a species may warrant listing under any of the five factors, we look beyond the species' exposure to a potential threat or aggregation of threats under any of the factors, and evaluate whether the species responds to those potential threats in a way that causes actual impact to the species. The identification of threats that might impact a species negatively may not be sufficient to compel a finding that the species warrants listing. The information must include evidence indicating that the threats are operative and, either singly or in aggregation, affect the status of the species. Threats are significant if they drive, or contribute to, the risk of extinction of the species, such that the species warrants listing as endangered or threatened, as those terms are defined in the Act.

As required by the Act, we conducted a review of the status of the species and considered the five factors in assessing whether the chimpanzee is in danger of

extinction throughout all or a significant portion of its range or likely to become endangered within the foreseeable future throughout all or a significant portion of its range. We examined the best scientific and commercial information available regarding the past, present, and future threats faced by the chimpanzee. We reviewed the petition, information available in our files, and other available published and unpublished information. We find that the chimpanzee is endangered by all five factors.

In 1990, wild chimpanzees were listed as endangered due to habitat loss, excessive hunting, capture for the pet trade, disease, and lack of effective national and international laws. Since then, threats to the chimpanzee have only expanded and intensified. Habitat that is needed to support viable populations is being lost to logging operations and conversion to agriculture. Individuals needed to maintain viable populations are being lost to hunting for the bushmeat trade, trade in pet chimpanzees, disease, and conflicts with humans.

Chimpanzees need large areas to provide sufficient resources for feeding, nesting, and shelter. Although some large forest blocks remain, logging and agricultural expansion have destroyed and fragmented much of the chimpanzee's habitat. The loss of suitable habitat is driving chimpanzees into smaller fragments of habitat closer to human settlements and creating competition for resources, increasing conflicts with humans, and increasing the risk of disease transmission. Human population growth and expansion of human activities have created a lucrative market for bushmeat and trade in live chimpanzees. Although chimpanzee meat constitutes only a small fraction of bushmeat found in markets, and the exact number of chimpanzees captured for the trade is unknown, these actions have drained chimpanzee populations. They are especially devastating because chimpanzees have slow reproductive rates and cannot easily recover from the loss of individuals. Laws exist throughout the range countries and internationally to protect the chimpanzee, but enforcement of national laws is lacking. Many populations are now small and isolated, putting them at a greater risk of extinction. Impacts to the chimpanzee are expected to continue into the future as the human population continues to expand and pressures on natural resources to meet the demands of the human population increase.

The status of the chimpanzee has not improved since the wild population of the species was reclassified from threatened to endangered in 1990. Threats to the species have intensified and expanded across its range. Therefore, we find that endangered is the correct status for the chimpanzee throughout its range. We also examined the chimpanzee to analyze if any other listable entity under the definition of ''species,'' such as subspecies or distinct population segments, may qualify for a different status. However, because of the magnitude and uniformity of the threats throughout its range, we find that there are no other listable entities that may warrant a different determination of status. Since threats extend throughout the entire range, it is unnecessary to determine if the chimpanzee is in danger of extinction throughout a significant portion of its range. Therefore, on the basis of the best available scientific and commercial information, we have determined that the chimpanzee meets the definition of an endangered species under the Act. Consequently, we propose to revise the listing of chimpanzees under the Act so that all chimpanzees, wherever found, are listed as endangered.

Special Rule

For threatened species, section 4(d) of the Act gives the Service discretion to specify the prohibitions and any exceptions to those prohibitions that are appropriate for the species, as well as include provisions that are necessary and advisable to provide for the conservation of the species. A special rule allows us to develop regulatory provisions that are tailored to the specific conservation needs of the threatened species and which may be more or less restrictive than the general provisions for threatened species at 50 CFR 17.31.

Currently, the captive chimpanzees in the United States, classified as threatened, are exempt from the general prohibitions for threatened species at 50 CFR 17.31 under a special rule for primates found at 50 CFR 17.40(c). Because special rules can be applied only to threatened species, the special rule for captive chimpanzees will no longer be available if the proposed revision to the classification of all chimpanzees to endangered is finalized. Therefore, we also propose to remove the chimpanzee, including a provision specific to the chimpanzee, from the special rule.

Available Conservation Measures

Conservation measures provided to species listed as endangered or threatened under the Act include recognition, requirements for Federal protection, and prohibitions against certain practices. Recognition through listing results in public awareness, and encourages and results in conservation actions by Federal and state governments, private agencies and groups, and individuals.

Section 7(a) of the Act, as amended, and as implemented by regulations at 50 CFR part 402, requires Federal agencies to evaluate their actions within the United States or on the high seas with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is being designated. However, given that the chimpanzee is not native to the United States, we are not designating critical habitat for this species under section 4 of the Act.

Section 8(a) of the Act authorizes the provision of limited financial assistance for the development and management of programs that the Secretary of the Interior determines to be necessary or useful for the conservation of endangered and threatened species in foreign countries. Sections 8(b) and 8(c) of the Act authorize the Secretary to encourage conservation programs for foreign endangered species and to provide assistance for such programs in the form of personnel and the training of personnel.

In 2000, the United States Congress passed the Great Ape Conservation Act to protect and conserve the great ape species, including the chimpanzee, listed under both the Endangered Species Act and CITES. The Great Ape Conservation Act granted the Service the authority to establish the Great Ape Conservation Fund to provide funding for projects that aim to conserve great apes through law enforcement training, community initiatives, and other conservation efforts. The Service's Wildlife Without Borders program, through the Great Ape Conservation Fund, is supporting efforts to fight poaching and trafficking in great apes; to increase habitat protection by creating national parks and protected areas; and to engage the community through local initiatives to conserve the most threatened great ape species.

The Endangered Species Act and its implementing regulations set forth a series of general prohibitions and exceptions that apply to all endangered and threatened wildlife. These prohibitions, at 50 CFR 17.21 and 17.31, in part, make it illegal for any person subject to the jurisdiction of the United States to ''take'' (take includes harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, collect, or to attempt any

of these) within the United States or upon the high seas; import or export; deliver, receive, carry, transport, or ship in interstate or foreign commerce in the course of commercial activity; or sell or offer for sale in interstate or foreign commerce any endangered or threatened wildlife species. To possess, sell, deliver, carry, transport, or ship any such wildlife that has been taken in violation of the Act is also illegal. Certain exceptions apply to agents of the Service and State conservation agencies.

Permits may be issued to carry out otherwise prohibited activities involving endangered and threatened wildlife species under certain circumstances. Regulations governing permits are codified at 50 CFR 17.22 for endangered species and 17.32 for threatened species. For endangered wildlife, a permit may be issued for scientific purposes, to enhance the propagation or survival of the species, and for incidental take in connection with otherwise lawful activities. For threatened species, a permit may be issued for the same activities, as well as zoological exhibition, education, and special purposes consistent with the Act.

Peer Review

In accordance with our policy, ''Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities,'' that was published on July 1, 1994 (59 FR 34270), we will seek the expert opinion of at least three appropriate independent specialists regarding this proposed rule. The purpose of such review is to ensure listing decisions are based on scientifically sound data, assumptions, and analysis. We will send copies of this proposed rule to the peer reviewers immediately following publication in the **Federal Register**. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and the data that are the basis for our conclusions regarding the proposal to list all chimpanzees as endangered under the Act.

We will consider all comments and information we receive during the comment period on this proposed rule during preparation of a final rulemaking. Accordingly, our final decision may differ from this proposal.

Required Determinations

Clarity of Rule

We are required by Executive Orders 12866 and 12988 and by the Presidential Memorandum of June 1, 1998, to write all rules in plain language. This means that each rule we publish must:

(a) Be logically organized;

(b) Use the active voice to address readers directly;

(c) Use clear language rather than jargon;

(d) Be divided into short sections and sentences; and

(e) Use lists and tables wherever possible.

If you feel that we have not met these requirements, send us comments by one of the methods listed in **ADDRESSES**. To better help us revise the rule, your comments should be as specific as possible. For example, you should tell us the names of the sections or paragraphs that are unclearly written, which sections or sentences are too long, the sections where you feel lists or tables would be useful, etc.

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that we do not need to prepare an environmental assessment, as defined under the authority of the National Environmental Policy Act of 1969, in connection with regulations adopted under section 4(a) of the Act for the listing, delisting, or reclassification of species. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Paperwork Reduction Act

This rule does not contain any new information collections or recordkeeping requirements for which Office of Management and Budget (OMB) approval is required under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). We may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

References Cited

A list of all references cited in this document is available at *http://www.regulations.gov* at Docket No. FWS–R9–ES–2010–0086, or upon request from the U.S. Fish and Wildlife Service, Endangered Species Program, Branch of Foreign Species (see **FOR FURTHER INFORMATION CONTACT**).

Authors

The primary authors of this proposed rule are staff members of the Branch of Foreign Species, Endangered Species Program, U.S. Fish and Wildlife Service.

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—[AMENDED]

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. Amend § 17.11(h) in the List of Endangered and Threatened Wildlife by:

■ a. Revising the entry for ''Chimpanzee (*Pan troglodytes*)'' (''Wherever found in the wild''); and

■ b. Removing the entry for ''Chimpanzee (*Pan troglodytes*)'' (''Wherever found in captivity'').

The revision reads as follows:

§ 17.11 Endangered and threatened wildlife.

* * * * *

(h) * * *

Species		Historic range	Vertebrate population where endangered or threatened	Status	When listed	Critical habitat	Special rules
Common name	Scientific name						
MAMMALS							
*	*	*	*	*	*		*
Chimpanzee	*Pan troglodytes*	Africa	Entire	E	16, 376	NA	NA
*	*	*	*	*	*		*

■ 3. Amend § 17.40 by:
■ a. Revising paragraph (c)(1); and
■ b. Removing paragraph (c)(3).
The revision reads as follows:

§ 17.40 Special rules—mammals.

(c) * * *

(1) Except as noted in paragraph (c)(2) of this section, all provisions of § 17.31 apply to the lesser slow loris *(Nycticebus pygmaeus);* Philippine tarsier *(Tarsius syrichta);* white-footed tamarin *(Saguinus leucopus*); black howler monkey *(Alouatta pigra);* stump-tailed macaque *(Macaca arctoides);* gelada baboon *(Theropithecus gelada);* Formosan rock macaque *(Macaca cyclopis);* Japanese macaque (*Macaca fuscata);* Toque macaque (*Macaca sinica);* long-tailed langur *(Presbytis potenziani);* purple-faced langur *(Presbytis senex);* and Tonkin snub-nosed langur *(Pygathrix [Rhinopithecus] avunculus).*

* * * * *

Dated: May 31, 2013.

Daniel M. Ashe,

Director, U.S. Fish and Wildlife Service.

[FR Doc. 2013–14007 Filed 6–11–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 697

[Docket No. 080219213–3470–01]

RIN 0648–AT31

Atlantic Coastal Fisheries Cooperative Management Act Provisions; American Lobster Fishery

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes new Federal American lobster regulations that would control lobster trap fishing effort by limiting access into the lobster trap fishery in Lobster Conservation Management Area 2 (Federal nearshore waters in Southern New England; Area 2), and in the Outer Cape Cod Lobster Conservation Management Area (Federal nearshore waters east of Cape Cod, MA; Outer Cape Area). Additionally, this action would implement an individual transferable trap program for Area 2, the Outer Cape Area, and Lobster Conservation Management Area 3 (Federal offshore waters; Area 3). The proposed trap transfer program would allow Federal lobster permit holders to buy and sell all or part of a permit's trap allocation, subject to the restrictions set forth in the proposed rule.

DATES: We must receive your comments no later than July 29, 2013.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2012–0244, by any of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2012-0244,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to: Peter Burns, Fishery Policy Analyst, Sustainable Fisheries Division, NMFS, 55 Great Republic Drive, Gloucester, MA 01930. Mark the outside of the envelope: ''Comments on Lobster Transferable Trap Proposed Rule.''

• *Fax:* (978) 281–9135; Attn: Peter Burns.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous). Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

You may obtain copies of the Draft Environmental Impact Statement (DEIS), including the Regulatory Impact Review (RIR) and the Initial Regulatory Flexibility Analysis (IRFA), prepared for this action at the mailing address specified above; telephone (978) 281–9180. The documents are also available online at *http://www.nero.noaa.gov/sfd/lobster.*

You may submit written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule to the mailing address listed above and by email to *OIRA_Submission@omb.eop.gov,* or fax to (202) 395–7285.

FOR FURTHER INFORMATION CONTACT: Peter Burns, Fishery Policy Analyst, phone (978) 281–9144, fax (978) 281–9135.

SUPPLEMENTARY INFORMATION:

Statutory Authority

These proposed regulations would modify Federal lobster fishery management measures in the Exclusive Economic Zone (EEZ) under the authority of section 803(b) of the Atlantic Coastal Fisheries Cooperative Management Act (Atlantic Coastal Act) 16 U.S.C 5101 *et seq.,* which states that in the absence of an approved and implemented Fishery Management Plan under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) (16 U.S.C. 1801 *et seq.*) and after consultation with the appropriate Fishery Management Council(s), the Secretary of Commerce may implement regulations to govern fishing in the EEZ, i.e., from 3 to 200 nautical miles (nm) offshore. The regulations must be (1) compatible with the effective implementation of an Interstate Fishery Management Plan (ISFMP) developed by the Atlantic States Marine Fisheries Commission (Commission) and (2) consistent with the national standards set forth in section 301 of the Magnuson-Stevens Act.

Purpose and Need for Management

The purpose of these proposed measures is to manage the American lobster fishery in a manner that maximizes resource sustainability, recognizing that Federal management occurs in consort with state management. To achieve this purpose, NMFS must act in response to the Commission's recommendations in several addenda to the Commission's ISFMP for American Lobster (Plan, Lobster Plan) to control lobster trap fishing effort in a manner consistent with effort control measures already implemented by the states. The proposed measures seek to (1) promote economic efficiency within the fishery while maintaining existing social and cultural features of the industry where possible, and (2) realize conservation benefits that will contribute to the prevention of overfishing of American lobster stocks.

Background

The American lobster resource and fishery is managed by the states and Federal government within the framework of the Commission. The role of the Commission is to facilitate cooperative management of interjurisdictional fish stocks, such as

American lobster. The Commission does this by creating an ISFMP for each managed species or species complex. These plans set forth the management strategy for the fishery and are based upon the best available information from the scientists, managers, and industry. The plans are created and adopted at the Commission Management Board level—e.g., the Commission's Lobster Board created the Commission's Lobster Plan— and provide recommendations to the states and Federal government that, in theory, allow all jurisdictions to independently respond to fishery conditions in a unified, coordinated way. NMFS is not a member of the Commission, although it is a voting member of the Commission's species management boards. The Atlantic Coastal Act, however, requires the Federal government to support the Commission's management efforts. In the lobster fishery, NMFS has historically satisfied this legal mandate by following the Commission's Lobster Board recommendations to the extent possible and appropriate.

The Commission has recommended that trap fishery access be limited in all Lobster Conservation Management Areas (LCMAs or Areas). The recommendations are based in large part on Commission stock assessments that find high lobster fishing effort as a potential threat to the lobster stocks. Each time the Commission limits access to an area, it recommends that NMFS similarly restrict access to the Federal portion of the area. NMFS received its first limited access recommendation in August 1999 when the Commission limited access to Areas 3, 4, and 5 in Addendum I. NMFS received its last limited access recommendation in November 2009, when the Commission limited access to Area 1 in Addendum XV. NMFS has already completed rules that limit access to Areas 1, 3, 4, and 5. This proposed rule responds to the Commission's limited access recommendations for Area 2 and the Outer Cape Area. It also responds to the Commission's recommendation to implement a trap transferability program in Areas 2 and 3 and the Outer Cape Area. The specific Commission recommendations, and NMFS's response to those recommendations, are the subject of this proposed rule and are discussed below.

Proposed Changes to the Current Regulations

1. Outer Cape Area

a. Outer Cape Area Commission Recommendation

In 2002, the Commission recommended that the states and NMFS limit entry into the Outer Cape Area based upon certain criteria developed by the Commission. The Commission adjusted the specifics of those criteria in 2008, and those adjusted criteria remain in place today. Specifically, the Commission recommended that the states and NMFS limit Outer Cape Area access to those permit holders who could demonstrate a prior fishing history (1999–2001) within the area. Further, the Commission recommended that the states and NMFS allocate traps to the qualifiers based upon ''effective traps fished'' during the years 2000–2002. In short, ''effective traps fished'' was to be the lower value of the maximum number of traps reported fished for a given year compared to the number of traps predicted to catch the reported poundage of lobsters for those years based upon a scientifically reviewed regression formula. The specific recommendations are contained in Commission Addendum III (February 2002) and Addendum XIII (May 2008).

The Commission's Outer Cape Area recommendations were the product of significant public debate and discussion. The Commission initiated discussion of Addendum III in July 2001 and sent a draft addendum to the various Area Lobster Conservation Management Teams (LCMTs) for discussion and refinement. An LCMT is a team of industry representatives—each Lobster Management Area has one LCMT—who provide industry expertise and perspective on potential management measures. The addendum was approved in draft form in October 2001 and presented in Commission public hearings in November 2001 before the Commission ultimately approved it at a public meeting in February 2002. Addendum XIII went through a similar public process before the Commission adopted it in May 2008.

NMFS responded to the Commission's Outer Cape recommendations with a public process of its own. Ever since the transfer of lobster management to the Commission, NMFS has notified Federal permit holders that regulatory actions in the lobster fishery could potentially involve limiting access to Federal Lobster Conservation Management Areas (64 FR 47756, September 1, 1999). Moreover, NMFS published an Advanced Notice of Proposed Rulemaking seeking comment on the issue on September 5, 2002 (67 FR 56800). When the Commission added effort control as a component of the Area 2 plan, NMFS published further Advanced Notices of Proposed Rulemaking documenting the agency's decision to combine the Outer Cape Cod and Area 2 limited entry program rulemakings and to separate the effort control rulemakings from lobster brood stock protection rulemakings (70 FR 24495, May 10 2005, and 70 FR 73717, December 13, 2005). Further, NMFS analyzed the Commission's recommendations in a DEIS made available to the public on May 3, 2010 (75 FR 23245). NMFS also presented its analysis at a series of DEIS public hearings from Maine to New Jersey, at which it received numerous comments. Those comments and NMFS' responses are set forth in this proposed rule.

b. Outer Cape Area—NMFS's Response to Commission Recommendations and Proposed Outer Cape Area Rule

NMFS proposes to limit access into the Outer Cape Area in a manner consistent with the Commission's recommendations. NMFS intends to qualify individuals for access into the Outer Cape Area based upon verifiable landings of lobster caught by traps from the Outer Cape Area in any 1 year from 1999–2001. Doing so will satisfy the Outer Cape Area Plan's purpose, as stated by the Commission in February 2002 (when the Commission approved the Outer Cape Area amendment) to ''. . . control the expansion of fishing effort in the Outer Cape Area and to establish Outer Cape trap levels at a targeted level (approximately 33,000 traps).''

The choice of 2001 as a cut-off year is reasonable for many reasons. First, Commission lobster limited access plans typically use a cut-off date after which access is restricted to avoid speculators from declaring into an area after-the-fact in an effort to gain access to an area that they typically did not fish. Second, area individuals knew or should have known about the potential date because the Commission's intentions were known at the time: Addendum III was drafted, debated, and the subject of public hearings in 2001. Third, and most importantly, the involved states have already used that same date as the cut-off for state lobster licenses, and NMFS' choice of that date will allow for better alignment between the states and Federal Government. The Commission Plan added qualifying years before the cut-off date (i.e., 1999 and 2000) to provide the fishing industry flexibility without subverting the plan's desire to

cap current effort. That is, in any given year, lobster fishers may have altered their fishing effort in response to external issues (e.g., health, family, and/or other personal reasons). An additional 2 qualifying years helps mitigate the potential for an allocation to be based upon an aberrant year's fishing history.

NMFS also proposes to allocate Outer Cape Area traps according to a Commission regression analysis formula that calculates effective trap fishing effort based upon verifiable landings of lobster caught by traps from the Outer Cape Area in any one year from 2000–2002. The Commission recommended using a different 3-year period at the request of Massachusetts' Director of Marine Fisheries, who at public hearings learned that use of the 2000–2002 data would better reflect existing effort and obviate the need for a hardship appeal process. The Commission's use of the regression formula in Addendum III and XIII to establish effective traps fished is also reasonable. In the absence of reliable trap effort data, state scientists sought to develop an effective method to predict the maximum number of traps fished. Since annual audits had shown that, on average, lobstermen more accurately reported their total lobster landings on their state data collection forms (1–2 percent variance), when compared to their reported maximum number of traps fished, a regression analysis was developed based on total reported lobster landings. The use of the regression formula removes the possibility that someone will benefit from simply reporting more traps than were actually fished. The Commission's Technical Committee peer reviewed the regression analysis, and although they noted the formula tended to favor full-time fishermen, the Technical Committee confirmed its validity. NMFS analyzed the formula and its rationale in the DEIS and concluded that the formula and its rationale were scientifically sound. NMFS also notes the importance of consistency in the state and Federal limited access programs, and that the potential for regulatory disconnects would be increased were the states and Federal government to allocate traps according to different criteria and formulas.

NMFS proposes two types of appeals to its Outer Cape Area Limited Access Program. The first appeal is a Clerical Appeal. The second is a Director's Appeal.

The Clerical Appeal would allow NMFS to correct clerical and mathematical errors that sometimes inadvertently occur when applications are processed. It is not an appeal on the merits and would involve no analysis of the decision maker's judgment. Accordingly, the appeal would not involve excessive agency resources to process. NMFS used an identical appeal with identical criteria to great success in its Area 3, 4, and 5 Limited Access Program.

The Director's Appeal would allow states to petition NMFS for comparable trap allocations on behalf of Outer Cape Cod applicants denied by NMFS. The appeal would only be available to Outer Cape Cod applicants for whom a state has already granted access. The state would be required to explain how NMFS's approval of the appeal would advance the interests of the Commission's Lobster Plan. The rationale for this appeal is grounded in the desire to remedy regulatory disconnects. NMFS knows that states have already made multiple separate decisions on qualification, allocation, and at least in some instances, trap transfers for the state portion of dually permitted fishers. NMFS is, therefore, faced with the task of making these same decisions and reaching identical results based upon Federal criteria that attempts to mirror the state criteria, which themselves might contain slight differences. As noted throughout the DEIS, the potential for regulatory disconnects is significant. While NMFS expects to achieve identical results for the vast majority of dually permitted fishers, it would be unreasonable to expect perfect matching in such circumstances. The Director's Appeal will help prevent the potential damage that such a mismatch could create.

The Director's Appeal would allow more effort to qualify and enter the fishery than would otherwise occur. NMFS, however, does not expect that this potential additional effort would negatively impact the fishery. First, the number of appeals is capped by the number of individuals who have already qualified under their state permit. These individuals, therefore, are already exerting fishing pressure on the lobster stock, albeit limited to state waters. Second, the DEIS analysis suggests good correlation between state qualifiers and potential Federal qualifiers. In other words, although some disconnects will likely occur, the DEIS predicts that the number will be relatively low. Finally, even if NMFS encounters a greater than predicted number of Director's Appeals, NMFS asserts that synchronicity is so crucial as to be the overriding factor in proposing the appeal.

The proposed rule also adopts the Commission's 2-month winter trap haul-out recommendation. The exact dates of the 2-month closure are less important than making sure that the Federal Outer Cape Area closure corresponds with the state Outer Cape Area closure. That is, so long as the state and Federal closures correspond, it matters less whether those dates are January 1st through February 28th, February 1st through March 31st, or some other 2-month combination. Here, NMFS follows the Commission's Addendum XIII recommendation to require removal of all traps from Outer Cape Area waters from January 15 th to March 15th. NMFS notes that Massachusetts is proposing a law that would adjust those closure dates to February 1st through March 31st. If the Massachusetts law passes, then NMFS would consider adjusting this proposed closure to that same time in its final rule.

There are numerous benefits to the trap haul-out provision, including benefits to lobster and marine mammals if trap gear is limited, as well as enforcement benefits. These benefits are discussed in greater detail in the response to Comment 22 in the Comment and Responses Section later in this proposed rule. The choice of the dates is reasonable because fishing effort is typically minimal during that time period. Failure to implement a similar trap restriction in the Federal Outer Cape zone could have deleterious effects because the restriction already exists in state waters. Accordingly, there would be great incentive for state-Federal dually permitted fishers to transfer their traps into Federal Outer Cape Area waters during the restricted season, thus greatly increasing effort there, absent similar Federal restrictions. The closure would apply only to traps set in the Outer Cape Area; those authorized to set traps in other areas would not be affected.

NMFS recognizes that establishing qualification and allocation criteria and drawing lines creates the potential for somebody to be left out. However, including additional or different qualification and allocation criteria in the Commission's Outer Cape Plan would create problems. First, doing so would introduce new variables that would have the potential to skew the Plan's ability to achieve its goals. Second, it would introduce a significant mismatch between the state and Federal Outer Cape Area limited entry programs wherein the state and NMFS could reach different determinations on identical permit histories. NMFS examined this issue extensively in its DEIS and concluded that disparate treatment of like individuals had the potential to so complicate future management as to render present and

future management measures (e.g., trap transferability) unworkable.

c. Outer Cape Area Potential Qualifiers

The NMFS DEIS predicts that approximately 26 Federal permits would qualify to receive an Outer Cape Cod Area trap allocation. This figure represents only 15 percent of the 170 permit holders who designated the Outer Cape Area as a potential fishing area on their permits in 2007. Of those 170 permit holders, however, only 38 purchased trap tags, which suggests that the vast majority (132 permits) designated the Outer Cape Area, but did not actively fish. Additionally, 12 of the 38 trap tag purchasers hailed from ports so distant from the Outer Cape Area that it seems unlikely that those 12 actively fished in the Outer Cape Area. The DEIS sets forth a detailed discussion on why an individual might designate an area without ever intending to fish there. Significantly, of the 26 individuals who designated the Outer Cape Area, ordered trap tags, and lived within steaming distance of the Area, the DEIS predicts that all 26 would qualify.

d. Outer Cape Area Rejected Actions

NMFS analyzed numerous alternatives to the Outer Cape Area proposed rule, including a ''no action'' alternative and qualifying lobster vessels but not allocating traps to them. Both were rejected as creating regulatory disconnects and potentially undermining the Commission's Lobster Plan. NMFS also considered but rejected qualifying SCUBA divers for trap allocations, in part because it would add new trap fishing effort from those (SCUBA divers) who did not fish with traps during the involved time period. A more detailed discussion of potential alternatives is identified in NMFS's DEIS [see **ADDRESSES**].

2. Area 2

a. Area 2 Commission Recommendation

In November 2005, the Commission recommended that the states and NMFS limit access into Area 2 to those lobster fishers who could document past fishing history in the Area. Specifically, the Commission recommended qualifying permit holders into Area 2 if they could document Area 2 landings history from 2001 to 2003. This landings history would be fed into a scientifically-reviewed regression formula to determine the number of traps allocated to the individual. If an Area 2 fisher had been incapable of fishing during the 2001 to 2003 fishing years, then that individual could apply for a hardship consideration that would allow them to use landings from 1999 and 2000 as the basis for qualification. The specific recommendations are contained in Commission Addendum VII (November 2005).

The Commission's Area 2 recommendation was the product of significant public debate that was even more involved than the public process that went into the creation of the Outer Cape Area Plan. The Area 2 Plan originated in October 2002, when the Lobster Board's scientific Technical Committee reported the basis of what ultimately was considered to be a lobster crisis in Area 2. The Board became so concerned about the poor condition of the lobster stock that it took emergency action in February 2003 (a gauge increase) as an immediate stop-gap measure while it developed a more thorough plan to respond to the situation. For more than 7 years, the Lobster Board and its sub-committees publicly deliberated over its Area 2 plan. The Board adopted measures (Addendum IV), then re-thought its position, rescinded measures (Addendum VI), proposed new measures (Addendum VII), then later added detail to the measures (Addendum XII). Because NMFS's Area 2 rulemaking is being done at the same time as its Outer Cape Area rulemaking, the Federal public process for the Area 2 plan is the same as was previously discussed for the Outer Cape Area.

b. Area 2—NMFS's Response to Commission Recommendations and Proposed Area 2 Rule

NMFS proposes to limit access into the Area 2 in a manner consistent with the Commission's recommendations. NMFS intends to qualify individuals for access into Area 2 based upon verifiable landings of lobster caught by traps from Area 2 from 2001–2003. The choice of the 2001–2003 time period reflects an effort to cap fishing effort in Area 2 as it existed while the Commission was developing its Area 2 Limited Access Plan. The dates also reflect an attempt to capture the attrition that occurred in the fishery during the downturn years in 2001–2003. Consequently, NMFS's Area 2 rationale is similar to the rationale it is employing in setting the access dates for the Outer Cape Area, by granting access to those with past trap fishing history, while excluding speculators and/or individuals who might have a history of Area 2 permit designations, but no actual fishing history in Area 2 during the qualification period.

NMFS also proposes to allocate traps according to a Commission formula that calculates effective trap fishing effort based upon landings during 2001, 2002, and 2003. The Commission chose landings as the appropriate metric because landings better reflected actual effort than the reported maximum number of traps fished. The Commission's Technical Committee peer-reviewed the regression analysis formula and, although they noted the formula tended to favor full-time fishermen, the Technical Committee confirmed its validity. NMFS analyzed the formula and its rationale in the DEIS and concluded that the formula and its rationale were scientifically sound.

NMFS proposes to adopt the Commission's recommendation to restrict allowable landings to those from ports in states that are either in or adjacent to Area 2, i.e., Massachusetts, Rhode Island, Connecticut, and New York. The Commission, in Addendum VII, found that the location of Area 2 prevented fishers from far away ports from actively fishing in Area 2. NMFS agrees with the Commission's conclusion.

NMFS proposes to adopt the Commission's recommended Hardship Appeal. Specifically, if an Area 2 fisher had been incapable of fishing during the 2001–2003 fishing years due to documented medical issues or military service, NMFS proposes to allow that individual to appeal the qualification decision on hardship grounds, allowing the individual to use landings from 1999 and 2000 as the basis for qualification. NMFS is also proposing a second appeal, the Director's Appeal, that would allow a state's marine fisheries director to petition for a trap allocation on behalf of a dual permit holder who was granted a state allocation but denied a similar Federal allocation. The Director's Appeal would be limited to those who qualified for a trap allocation under the state program, but who were denied that allocation under the Federal program. The third Area 2 appeal would be a clerical appeal. Both the Director's Appeal and Clerical Appeal are identical in form and rationale to the Director's Appeal and Clerical Appeal being proposed for the Outer Cape Area. NMFS acknowledges the potential for appeals to create unwieldy loopholes that undermine the rule, but the DEIS analysis suggests that few permit holders would need to avail themselves of such an appeal. Further, DEIS analysis suggests reasons for even greater concern should NMFS diverge from the states and not attempt to implement appellate criteria that would assist in state-federal compatibility.

c. Area 2 Potential Qualifiers

NMFS's DEIS predicts that approximately 207 Federal permit holders will receive a Federal Area 2 allocation. This figure represents approximately 48 percent of the 431 permit holders who designated Area 2 on their permits in 2007. Of those 431 permit holders, however, only 182 purchased trap tags, which suggests that the majority (249 permits) designated Area 2 but did not actively fish there (or anywhere else). Even more significant is the DEIS finding that of the 182 Federal permit holders that both designated Area 2 and purchased trap tags in 2007, approximately 167 permit holders would qualify—a figure that suggests over 90 percent of the present Area 2 fishers fished during the qualification years and would still be allowed to fish Area 2 with traps in the future.

d. Area 2 Rejected Actions

NMFS analyzed numerous alternatives to the Area 2 proposed rule, including a no-action alternative, and qualifying participants, but not assigning them individual trap allocations. Both of these alternatives were rejected as creating regulatory disconnects, and potentially undermining the Commission's Lobster Plan. NMFS's DEIS contains a more detailed discussion of potential alternatives.

NMFS also chooses to put off the Commission's recommended Area 2 ownership cap. This cap would limit the number of Federal lobster permits that an Area 2 participant could own at any one time. At this time the Commission does not appear to have reached a definitive policy on ownership caps. For example, ownership cap options were included in Commission draft Addendum XVIII, but were pulled out of the addendum before it was approved in August 2012. NMFS intends to participate in the Commission's dialog on this issue, but NMFS asserts it imprudent to implement such a cap before the Commission completes its deliberation.

3. Individual Transferable Trap Program (ITT, Trap Transfer Program)

a. ITT Commission Recommendation

In February 2002, the Commission recommended a first of its kind Trap Transferability Program in the Outer Cape Area. The initial recommendation was overly simplistic, which hampered its implementation. In short, the Commission sought to allow qualified Outer Cape permit holders to buy and sell their trap allocations during a designated time period up to certain trap cap.

The Commission followed its Outer Cape Transferability Plan with new trap transfer plans in two other areas: One for Area 3; another for Area 2. With each recommendation, the Commission's transferability plans became more detailed. All recommendations, however, contain the following three basic elements: (1) Individuals could buy and sell traps up to a set trap cap during a designated time period; (2) only individuals with qualified area allocations could sell traps; and (3) each trap transfer would be taxed by 10 percent, payable in traps.

The specific Outer Cape recommendations are set forth in Addendum III (February 2002) and XIV (May 2009). The Area 3 recommendations are contained in Addenda IV (January 2004), V (March 2004), and XIV (May 2009). The Area 2 recommendations are contained in Addendum VII (November 2005) and Addendum IX (October 2006).

Each area trap transfer plan was crafted after considerable public debate and comment. Industry-based Lobster Conservation Management Teams in Areas 2, 3, and Outer Cape Area were the original proponents and architects of their respective area plans. The plans were further refined in public meetings and hearings by the Lobster Board. Ultimately, after Board approval, the trap transfer plans were forwarded to NMFS, at which time additional public notice and hearing occurred. Because NMFS's Trap Transfer rulemaking is being done at the same time as its Area 2 and Outer Cape Area rulemaking, the Federal public process for the Trap Transfer Plan is the same as was previously discussed for the Area 2 and Outer Cape Area limited access plans.

b. ITT Program—NMFS's Response to Commission Recommendations and Proposed ITT Rule

NMFS proposes to implement trap transfer programs in Areas 2, 3, and the Outer Cape Area in a manner consistent with the Commission's recommendations. NMFS intends to offer an optional trap transfer program in Areas 2, 3, and the Outer Cape Area. The program would allow qualified permit holders to sell portions of their trap allocation to other Federal permit holders. Buyers could purchase traps up to the area's trap cap, with 10 percent of the transferred allocation debited and retired from the fishery as a conservation tax. NMFS asserts that a trap transfer program is reasonable and will help mitigate the economic impacts to individuals who do not qualify, or who qualify, but only for a small allocation. In other words, individuals could increase their allocation by purchasing additional traps through this program. As a result, the proposed trap transfer program will allow buyers and sellers to scale their businesses to optimum efficiency.

NMFS does not, however, view the trap transfer programs without concern. As a preliminary matter, trap transferability has the theoretical potential to increase actual trap effort. Specifically, qualified lobster fishers could maximize their income by transferring ''latent'' traps—the portion of their allocation that they might not be using—to other fishers who would use the allocation more actively, thereby increasing the overall level of fishing effort. This theoretical increase, however, will not likely be seen on the water (see responses to Comments 7, 13, and 14). Nevertheless, NMFS proposes to offset this potential impact by implementing a conservation tax on trap transfers to retire 10 percent of the traps included in the transfer. The DEIS examined this issue, as well as other potential counter measures. NMFS expects that, on balance, the proposed measures will afford appropriate balance against undue activation of latent effort.

The use of area trap caps is another measure that restricts the potential to increase effort through trap transfers. In short, this proposed rule would restrict transfers so that permit holders may not receive a trap allocation that would put their overall trap allocation above the area trap cap. The trap cap in Area 2 and the Outer Cape Area is 800 traps. Area 3 has numerous trap caps, depending upon the allocation bin into which the Area 3 permit holder initially qualified. The highest Area 3 trap cap is 1,945 traps. Commission Addendum XIV and Addendum XVIII, however, make it clear that the Commission intends to have a single universal trap cap in Area 3. NMFS, therefore, proposes to set the Area 3 trap cap at 1,945 traps. NMFS notes that the Commission and Area 3 LCMT are in discussions about either increasing or decreasing that trap cap. NMFS will consider modifying the Area 3 trap cap if and/or when the Commission and Area 3 LCMT have completed their discussions and recommend amendments to NMFS.

Yet another measure to offset effort expansion is NMFS's proposal to allow three-party transfers involving dual state and Federal permit holders. This proposal differs from the Commission's proposal to limit trap transfers to a bin system that restricts a dual state and

Federal permit holder to transferring only with another dual permit holder of that same state. Under the Commission's system, permit holders from states with few qualifiers would find their participation options limited, and the economics skewed toward the few with allocations. NMFS's Trap Transfer Program, however, would allow a dual state and Federal permit holder to purchase Federal trap allocation from any other dual Federal Lobster permit holder. NMFS would still require that the transferring parties' state/Federal allocation be synchronized at the end of the transaction. Accordingly, a dual permit holder could purchase a Federal allocation from an individual in another state, as well as an equal state-only allocation from a third individual in his or her own state and the resulting allocation numbers for that dual permit holder would match. In such a scenario, there would be no added trap effort to the dual permit holder's state, but there would be a decrease of trap fishing effort in the state waters of the dual permit holder selling the original state/Federal trap allocation.

NMFS's greatest concern with a Trap Transfer Program is that it heightens the potential for regulatory disconnects. Regardless of which limited access option NMFS ultimately chooses, there will, undoubtedly, be a certain number of dually permitted lobster fishers—i.e., individuals fishing under both a state and a Federal permit—for whom the state and Federal decision-making will not align; they will either be qualified by one jurisdiction, but not another, or qualified by both, but allocated different numbers of traps. Although the DEIS confirms that the number of disconnects under the proposed rule will likely be small and of negligible impact to the overall limited access programs, creating additional layers of decision-making— i.e., trap transfers—has the potential to exacerbate disconnects with each successive transfer.

NMFS believes it can resolve the regulatory disconnect problem by requiring that potential participants agree to certain parameters before opting into the Trap Transfer Program. The Trap Transfer Program is not mandatory; rather, interested participants can choose to opt in. Any participants holding both state and Federal lobster permits (''dual permit holders'') with different trap allocations would have to agree to abide by the lower of the two trap allocations to take part in the program. In this way, permit holders would not be obliged to forfeit their higher trap allocation, but they would not be able to participate in the transferability program if they chose to retain it. This alternative would synchronize the dual permit holder's allocations at the initial opt in time, thus greatly facilitating the tracking of the transferred traps. Further, as trap allocations are transferred, a centralized trap transfer data base accessible by all jurisdictions will keep track of trap transfers, thus ensuring that all jurisdictions are operating with the same numbers at the beginning and end of every trap transfer period. The centralized trap transfer database is being created by the Atlantic Coastal Cooperative Statistics Program (ACCSP) and is a critical, foundational prerequisite to the Trap Transfer Program. As of the date of this proposed rule, the database has not been finalized and its progress bears watching. NMFS analyzed potential trap transfer programs in its DEIS and, assuming that the database is complete and functioning as designed, NMFS found the proposed Trap Transfer Program to be the most prudent of the alternatives.

Finally, the timing of the Trap Transfer Program is also of great concern. Industry and Commissioners are counting on trap transferability as a foundational element of their business and management plans and cannot move forward on these plans until NMFS implements its Trap Transfer Program. Accordingly, they urge NMFS to start its Trap Transfer Program as soon as reasonably possible (see Comment 8 in comment/response section below). However, the details of how this program will operate are not yet completely known. First, the Commission's Trap Transfer Program is novel and will require intensive coordination at state and Federal levels. Such coordination would involve, at a minimum, a trap tracking system, i.e., the ACCSP's centralized trap transfer data base, that has been tested and upon which state and Federal managers have been trained. As discussed above, however, the centralized trap transfer data base remains under development and, therefore, the state-Federal coordination protocols are, as yet, unwritten. Second, before traps can be transferred, they must first be allocated, yet doing so will take time. NMFS expects that it will be able to qualify and allocate traps for the majority of Area 2 and Outer Cape Area trap fishers quickly, but future developments could easily delay the qualification and allocation process. NMFS is concerned that beginning the Trap Transfer Program without having first processed a majority of its qualification applications will complicate the trap transfer market and create derby-style pressures in the qualification/allocation process. It might also cause NMFS to have to siphon off resources from the qualification process to satisfy the transfer process, leaving neither process with sufficient resources. Ultimately, NMFS proposes to begin the first year of its Trap Transfer Program 120 days after the publication of its final rule, which NMFS expects is a sufficient amount of time for it to complete the majority of its qualification and allocation decisions. Whether the time period should be advanced (e.g., 90 days after the final rule) or delayed (e.g., 180 days after the final rule, or longer) will depend in large part on the development of the as yet incomplete infrastructure necessary to carry out the program. NMFS is greatly interested in any comments from the public, the states, and Commission on this timing issue.

c. Potential ITT Participants

At present, there are 3,152 Federal Lobster Permits. This proposed rule would allow any of these permit holder to purchase Area 2, 3, or the Outer Cape trap allocations through the Trap Transfer Program. Accordingly, any of the 3,152 individuals with a Federal Lobster Permit could opt into the proposed Trap Transfer Program and purchase qualified and allocated traps.

NMFS gave careful consideration to its proposal to allow all Federal Lobster Permit holders to purchase trap allocations. While there is some utility in limiting the number of participants fishing in an area, there exist numerous reasons to open the Trap Transfer Program to all Federal Lobster permit holders. First, a primary purpose in limiting fishery access is to limit trap fishing effort, which will have been done regardless of who is ultimately allowed to transfer traps. That is, if the total overall trap allocation for an LCMA is set, there is less biological importance to which, or how many, permit holders fish that allocation. Second, allowing all permit holders to purchase allocated traps helps to offset potential negative impacts to those individuals who did not initially qualify into the area. Third, allowing unqualified buyers to purchase allocated traps allows younger, newer lobster fishers to enter the fishery in a scaled fashion, which was a desire voiced to NMFS by the lobster industry during the DEIS public hearings. Fourth, the greater the number of potential buyers, the greater the market and potential transactions, and thus the greater the potential biological benefit through the 10 percent trap conservation tax.

Notably, the proposed rule restricts trap transfers for individuals that have also qualified into Area 1. Specifically, although Area 1 permit holders may opt into the Trap Transfer Program and transfer traps, doing so may result in a forfeit of that permit holder's ability to fish in Area 1 to the extent that person sells or transfers away part of his or her trap allocation. This prohibition originally involved Area 1 being the last open access lobster area at the time the Commission was developing its trap transfer recommendations (i.e., 2002–2010). At that time, there was concern that as other areas limited fishing access, displaced fishing effort would flood into Area 1 because Area 1 was open access; i.e., anybody with a Federal lobster permit could designate Area 1 on their Federal lobster permit and fish with 800 traps. The fear was that an individual would sell their entire Area 2, 3, or Outer Cape Area trap allocation and then move their business to Area 1 and start fishing with another 800 traps, effectively doubling effort. Since that time, however, Area 1 developed and implemented a limited access program in their area. As a result, Area 1 is no longer open access and Area 2, 3, and/or Outer Cape Area permit holders will not be able transfer traps and start fishing anew in Area 1. Accordingly, the concern is now largely moot. One problem, however, remains: Although the 800 trap limit applies to all Federal permit holders in Area 1, there is no individual permit-based Area 1 trap allocation. As such, there is no Area 1 allocation to debit should a multi-area qualifier (i.e., a person who has qualified into Area 1 as well as another area) sell allocated traps from that other area. Consequently, an Area 1 fisher who also qualified into other areas could transfer their Area 2, 3, and/or the Outer Cape Area allocation and still fish with 800 traps in Area 1. This would create an overall increase in trap fishing effort beyond what was historically fished. A simple regulatory fix—e.g., giving all Area 1 participants an individual 800 trap allocation—could resolve this issue, but the Commission has not, as yet, amended its earlier recommendation to NMFS. Accordingly, this proposed rule retains the Commission's original recommendation that Area 1 qualifiers be allowed to purchase transferable traps from Areas 2, 3, and the Outer Cape; however, by selling any of their transferable allocation, they would forfeit their eligibility for Area 1 trap fishing because the Area 1 allocation cannot be equally reduced along with the transferable allocation if transferable traps are sold.

d. ITT—Rejected Actions

NMFS analyzed numerous alternatives to the proposed Trap Transfer rule, including a no-action alternative, allowing the program only in Area 3, and implementing the Commission's Trap Transfer Program. The Commission's Trap Transfer Program is substantially identical to NMFS's proposed program, except that the Commission's program is immediately and automatically open to all participants. Accordingly, because permit holders can participate in the Commission's program without opting in, the Commission's program lacks the synchronizing mechanism that NMFS proposes. The other above-mentioned alternatives reduce the potential for regulatory disconnects, but offer none of the proposed program's mitigation benefits. A more detailed discussion of potential alternatives is identified in NMFS DEIS, section 4.4.

NMFS also rejected the Commission's proposal to tax full business transfers at 10 percent. As a preliminary matter, full business transfers have been happening for decades and are independent of trap transferability. Second, the greatest number of full business transfers occur, not surprisingly, in Area 1, which is the Lobster Management Area with the largest number of permit holders. As discussed above, however, Area 1 does not have a trap allocation from which to apply a 10 percent trap transfer retirement tax. Applying a tax, therefore, is not feasible under existing regulations. Further, NMFS notes that the Commission is continuing to deliberate upon what it considers to be a separate business entity for the purpose of determining ownership caps. NMFS will monitor these deliberations and as the issue evolves will consider additional recommendations on the matter should the Commission determine it necessary.

4. Regulatory Streamlining

NMFS proposes to remove certain old, out-dated paragraphs of regulatory text from its Federal Lobster Regulations. Specifically, this action would remove the Area 3, 4, and 5 qualification and appeals criteria from § 697.4 and remove outdated sections of the trap cap regulations in § 697.19. The Area 3, 4, and 5 limited access program qualification and allocation process was completed many years ago (the last appeal being finalized in approximately 2006). The paragraphs to be removed from § 697.19 also relate to outdated trap cap provisions (e.g., trap caps before and after August 2003). In short, the principal measures in this proposed rule (i.e., limited access programs in Area 2 and the Outer Cape Area, as well as a Trap Transfer Program) caused NMFS to review § 697.4 and § 697.19 and identify paragraphs that are old, irrelevant, and that bog down the reader. Removing these paragraphs will keep the regulations fresh and assist the public's understanding of the section going forward.

Related Lobster Rulemakings

The measures taken in the Lobster Plan are separate efforts that are designed to build off of one another so that the overall whole is greater than the sum of its parts. The Lobster Plan is also ever-changing, which as noted in the DEIS can present challenges to NMFS. Often, the Commission builds upon its Plan so quickly that its recommendations become bedrock Lobster Plan principles and the foundation of future measures that are often recommended before NMFS can complete its analysis of the initial recommendation. Such is the case here.

There are two general categories of measures that the Commission has or will likely recommend to NMFS for future rulemaking. This proposed rule would be consistent with both categories of measures. The first category relates to the Commission's response to the to the Southern New England stock recruitment failure. The Commission decided to address the recruitment failure in two phases: First, by reducing lobster exploitation by 10 percent; and, second, by reducing effort by 50 percent in Area 2 and 25 percent in Area 3, the principal southern New England Stock areas. The Commission's measures to reduce exploitation by 10 percent include changing the minimum and maximum size limits for harvestable lobster and/or implementation of closed seasons. The measures to reduce effort by 50 percent include an immediate 25 percent trap allocation reduction, for Area 2, followed by 5 years of trap allocation reductions at 5 percent reductions per year. For Area 3, traps will be reduced by 25 percent in total, with 5 percent reductions per year for 5 consecutive years. This proposed rule not only complements these other potential rulemakings, but failure to implement the proposed rule might actually undermine Commission efforts in these other matters. For example, the Commission's willingness to implement a 10 percent exploitation reduction largely depended on its willingness to implement subsequent trap cuts in Areas 2 and 3. The trap reductions

depend on affected fishers being able to mitigate the impacts of such cuts by purchasing additional trap allocation through trap transfers, and in turn a trap transfer program depends on there being a limited access program in the involved lobster management areas.

The second category of potential recommendations involves measures to more finely tune the Trap Transfer Program. These measures could include capping the number of permits (i.e., determining what ''ownership'' means and then capping permit ownership levels), changing trap caps in Area 3, as well as creating a trap banking program, which would allow fishers to purchase trap allocations above their trap cap and place them in a bank where they would not be fishable unless their overall trap allocation number fell below the area trap cap. These potential measures are still being deliberated upon by the Commission, but largely depend on NMFS implementing a Trap Transfer Program as proposed in this rule.

Comments and Responses

Comment 1: One individual expressed their displeasure on the length of time it has taken to implement this rulemaking.

Response: NMFS understands and, to an extent, even shares in this frustration. It is important to understand, however, that lobster rules are not made in isolation. Changing circumstances in the fishery have necessitated a slower, more deliberate pace. For example, since receiving the Commission's first rulemaking recommendation, the Commission has declared an emergency on an area lobster stock (the Southern New England (SNE) lobster stock in 2003). Then, in 2010 the Commission declared a lobster recruitment crisis on that same lobster stock. The Commission and commentators alike urged NMFS to delay its rulemaking process until the crisis was better understood. Further, the Commission's rulemaking recommendations have themselves changed: The Outer Cape Plan, initially approved in Addendum III in 2002, was amended by Addendum XIII in 2008. The Area 2 Plan was approved in 2003 (Addendum IV), rescinded in 2006 (Addendum VI), and a new plan approved in later that year (Addendum VII). Important details to all plans (including transferability) were not added until 2009 (Addendum XII). Ultimately, given the ever-changing context, NMFS has been forced to proceed in a more cautious, deliberate fashion, which although perhaps frustrating in the time it takes, nevertheless appears to be the most prudent approach.

Comment 2: A number of commenters noted that NMFS was ''several years behind'' in implementing the Commission's Plan and urged that NMFS proceed with this rulemaking, as its measures were already being implemented in state waters and compatible measures are needed in Federal waters.

Response: NMFS understands that implementation delays by the states and NMFS can make it more difficult for the Commission to plan new measures to respond to new crises. Lobster management is not a static process; new issues are always arising. Often, by the time the Commission completes one part of its Lobster Plan, additions, edits, and amendments to that same part are already in development. In fact, the Commission's Lobster Plan sometimes builds upon itself so quickly that new Plan measures are sometimes adopted that depend on earlier Plan measures, which have not yet been analyzed, much less adopted, by NMFS. Nevertheless, a speedy response is not always the best response. A balance needs to be struck because hastily crafted plans can have unintended and unwelcome consequences. Quite often, in attempting to more speedily address lobster issues, the Commission's Lobster Board left out important plan details to be addressed at some later date. For example, although the Commission recommended the rudiments of its Outer Cape Area limited access program and trap transferability in 2002 and the Area 2 limited access program in 2004, critically important details were not added until later (see e.g.: Addendum V–2004; Addendum VII–2005, Addendum IX–2006, Addenda XII & XIV–2009). Fortunately, the later added details were within the scope of what had been originally proposed (limited access program based upon past participation in the fishery) and thus NMFS did not need to start the rulemaking over. Now that those added details are known, and now that the SNE stock crisis is better understood, NMFS is better able to proceed with this rulemaking.

Comment 3: In public meetings of the SNE stock crisis and Addendum XVII deliberations in 2010 and 2011, the Commission's Lobster Board noted that the SNE stock crisis introduced tremendous uncertainty into lobster management, which complicated and delayed complementary Federal rulemaking until the crisis was better understood and the potential Commission response became clearer.

Response: NMFS agrees and notes that the originally recommended Lobster Board response to the SNE crisis in 2010 suggested a 5-year moratorium on lobster fishing—an option some on the Board described as a ''nuclear option'' because of its potential to put many fishers out of business and radically change the character of the SNE fishery. To proceed with this rulemaking at such a time seemed counter-productive and ill-advised (e.g., would potentially qualified permit holders even bother to apply for entry into a fishery in the midst of a 5-year moratorium?). As such, NMFS felt it imprudent to proceed with this rulemaking in the face of such widely varied and uncertain responses. The Commission, however, now has a strategy to respond to the SNE lobster stock crisis and approved the first phase of that response in February 2012 (Addendum XVII). The second phase of the response is identified in draft Addendum XVIII. Accordingly, NMFS now has a better understanding of the state of the fishery—both biologically and managerially—and the agency is able to continue on with its rulemaking.

Comment 4: One industry representative indicated that concerns over the SNE lobster stock made it difficult to comment on ''where transferability should be going or how it should end up.'' They urged that NMFS proceed cautiously with this rulemaking.

Response: NMFS agrees and notes that the commenter's recommendation was repeated by members of the public during past Commission Lobster Board meetings. It was not possible to proceed more quickly given the number of additions that the Commission made to its plan and given the potential plan changes that the Commission were contemplating as recently as 2012. Nevertheless, delays are always a concern insofar as they have the potential to render a rulemaking stale and cause stakeholders to disengage from the process. NMFS, however, does not consider that to have happened here. Throughout this process, stakeholders have been continually reminded of the proposed measures, be it through the numerous agency **Federal Register** Notices, or reminders in permit holder letters, or through the agency's DEIS public hearings conducted in the Northeast in 2010. Additionally, the limited access and transferability plans have been reported steadily in the news media. The recent SNE stock recruitment failure generated tremendous interest in this rulemaking, not only from the lobster industry, but from their representatives in

government, managers, non-governmental organizations, and the public in general. In addition, most of the affected Outer Cape Area and Area 2 Federal Lobster permit holders recently underwent a similar limited access program application process with their state permits. Accordingly, NMFS asserts that this rulemaking remains fresh and current with the stakeholders actively engaged. The delays, while frustrating, were unavoidable and necessary to draft a workable proposed rule.

Comment 5: Numerous commenters, both in writing and at the DEIS public hearings, supported the rule's proposed limited access measures, and further urged that NMFS enact rules that mirror the states' rules as closely as possible to avoid regulatory disconnects.

Response: NMFS's DEIS analysis supports such comments. NMFS believes that creating an Area 2 and Outer Cape Area limited entry program that is substantially identical and coordinated with the Commission's limited entry program offers the most prudent way forward for the lobster fishery in those areas. In fact, failing to do so would likely create a mismatched and disconnected management program that could undermine and even threaten fisheries management in those areas. Regardless, despite the greatest efforts of NMFS, the Commission, and the states to have identical programs, some differences and some discrepancies will undoubtedly occur. NMFS's analysis, however, suggests that the number of disconnects will be few and have negligible social and environmental impacts. Nevertheless, this proposed rule includes additional elements, such as a Director's Appeal and a voluntary Trap Transfer Program, which would allow NMFS and the states to further coordinate and reconcile irregularities should they occur on individual permits. These additional elements are discussed in greater detail in Comment 20.

Comment 6: One state agency wrote in support of NMFS's proposed Trap Transfer Program and explained that such a program was critical to the success of the overall limited access plan. The state indicated that effort control plans sometimes resulted in fishermen being allocated far fewer traps than they desired or needed. The ''relief valve'' to accommodate some individual fisherman's need to increase trap allocation was the Trap Transfer Program.

Response: NMFS analyzed this issue in detail in its DEIS and agrees that its proposed Trap Transfer Program would allow individual lobster businesses the flexibility to scale their business up or down according to individual business plans. Obviously, not all lobster businesses fish the same number of traps. Although an increase in the number of traps fished may increase the amount of lobster harvested, it will also increase fishing costs, including costs for bait, fuel, and time to tend the additional traps. Each fishing business calculates the benefits and costs of fishing at certain trap levels when deciding how many traps to fish. In this proposed rule, however, initial trap allocations will be based on levels of participation during a qualification period that occurred in the past. The qualification period does not factor into what the lobster fisher is fishing presently or what the fisher may want to fish in the future. As a result, some vessels may receive allocations that do not reflect their current business plan, with some receiving higher trap numbers and others receiving lower. Transferability will make it possible for trades to take place, thereby allowing lobster fishers a better chance to scale their businesses to their most appropriate and economically viable level.

Comment 7: Numerous lobster fishers and lobster businesses commented in favor of NMFS's proposed Trap Transfer Program. They point out that failure to implement a Federal Trap Transfer Program will have serious negative consequences for the inter-jurisdictional management of the fishery. The Trap Transfer Program increases flexibility for lobster businesses and that benefit far outweighs the biological negative of increased trap production by breaking large inefficient trap allocations and transferring them to businesses that will make them more productive.

Response: NMFS analyzed this issue in its DEIS and concluded that the proposed Trap Transfer Program makes good sense and will be an overall benefit to the fishery. Specifically, the Trap Transfer Program would likely improve the overall economic efficiency of the lobster industry by allowing businesses to scale up or down according to whatever trap number works best for their particular business. For example, some previously inactive traps, i.e., traps that were not being fished (''latent traps''), could be sold to individuals who would likely fish the traps more actively. Theoretically, doing so might increase effort in the area, although likely not on a scale that would produce negative impacts on the lobster population (see responses to Comments 13 and 14). NMFS's proposed rule, however, includes trap transfer taxes (which would retire 10 percent of the traps involved in any transfer) and trap caps on the number of traps a business could accumulate, to balance against the activation of latent effort. NMFS asserts that these protection measures mitigate the possibility for an increase in trap effort. NMFS further notes that Commission Addendum XVIII calls for further trap cuts in SNE, and provides an additional buffer against the possibility of increased effort due to the activation of previously latent traps.

Comment 8: Members of industry and the Commission asked that NMFS implement its Trap Transfer Program as soon as reasonably possible.

Response: NMFS considered many alternative start times before deciding that its preference is to start the program 120 days after the publication of the final rule. Many alternatives exist. On one extreme, NMFS could attempt to begin the Trap Transfer Program immediately in Area 3 (where trap allocations have already been decided), and then begin it in Area 2 and the Outer Cape Areas on a continuing, rolling basis as the permit holders are qualified. Such an alternative, while speedy, has significant down-sides. For example, were Area 3 to transfer traps before the other areas, it could create disconnect issues because many Area 3 traps will also likely be qualified into Area 2 and Outer Cape Area. Further, giving one group a head start over another group—especially allowing Area 2 and Outer Cape Area qualifiers to enter the program on a first come, first served basis—could create a race to transfer that might unduly advantage early qualifiers and skew market forces. At the other extreme is an alternative that delays the Trap Transfer Program until NMFS makes initial decisions on every Area 2 and Outer Cape Area application and/or appeal. Waiting would allow NMFS to start the Trap Transfer Program with all participants on equal terms, and would likely allow NMFS to proceed at a more deliberate, thoughtful, and less chaotic pace. However, NMFS's lobster limited access program experience in other areas (i.e., Areas 1, 3, 4, and 5) suggests that it often takes years to finish making decisions on all applications and all appeals. Delaying trap transfers until all limited access decisions are made would create unacceptable delays to permit holders relying on the Trap Transfer Program and to lobster managers who are waiting for the Trap Transfer Program so they can implement other lobster management measures.

Ultimately, NMFS proposes a middle ground alternative: Beginning the Trap Transfer Program in all three areas 120

days after the publication of the final rule. NMFS's lobster limited access program experience suggests that it will be able to process and complete the great majority of the applications in 120 days. This would allow the Trap Transfer Program to begin with a larger group of initial qualifiers and, thus, allow the program to proceed under more normal market conditions. Ultimately, however, the program's start time will be heavily dependent upon infrastructure being in place to properly account for and manage the transfers. At present, the ACCSP is in the process of developing a tracking system to account for all transfers. That system, however, has not yet been completed.

Comment 9: Numerous commenters were concerned about discrepancies between an individual's potential state and Federal trap allocations. These individuals supported NMFS's alternatives—such as the proposed voluntary Trap Transfer Program—that would synchronize state and Federal allocations. These commenters also uniformly agreed with the need for a centralized trap transfer data base so that all transfers could be catalogued and tracked by all relevant jurisdictions.

Response: NMFS agrees that it is critical to synchronize the state and Federal limited access and transferability programs to the greatest extent practicable. NMFS's DEIS analysis indicates that the threat presented by incongruent state and Federal regulatory programs is significant and real. This is, in fact, one of the many reasons in support of a Federal Trap Transfer Program—i.e., if the states allowed trap transfers (the states have already approved trap transferability programs of their own), but NMFS did not, then trying to follow and determine the number of traps on a state/Federal dually-permitted entity's allocation would quickly become an impossible task as that individual transferred his or her state allocation. NMFS's proposed Trap Transfer Program follows the trap transfer recommendations in the Commission addenda, including Addendum XII, and thus is substantially identical to the trap transfer programs of the states. To the extent that discrepancies occur, NMFS's Trap Transfer Program attempts to synchronize with the states by mandating that participants reconcile their state and Federal trap allocations before they are allowed to transfer traps. NMFS agrees that a centralized database is necessary to keep track of all transfers and the agency has actively advocated for such a database in Commission Lobster Board discussions.

Comment 10: Lobstermen at the DEIS public hearing in Narragansett, Rhode Island (June 2, 2010), expressed concern that management restrictions were going to cause this already aging industry to further lose its youth and vitality. As access to lobster permits and fishing areas becomes increasingly restricted (especially with that access being determined by fishing history that potentially occurred before younger fishers may have begun fishing in earnest), younger lobstermen have the potential to be squeezed out, both because they are newer and thus lack the history, and because they are younger and often lack the up-front capital to buy whole fishing operations.

Response: NMFS's proposed Trap Transfer Program should benefit young lobstermen such as those who commented at the DEIS public hearing in Narragansett, Rhode Island. The proposed Trap Transfer Program would allow participants to build up their businesses as time and capital allow (e.g., newer fishermen could start with smaller numbers of traps and build up) instead of having to incur the great expense of buying a whole, fully-established business all at once. In other words, any Federal lobster permit holder could buy into an area regardless of whether they initially qualified into that area (e.g., again, starting with a smaller, less expensive business plan that allows for expansion if necessary), which would allow younger individuals access to an area despite potentially lacking the requisite fishing history to initially qualify into that area.

Comment 11: Some people expressed concern at NMFS's DEIS public hearings that the proposed Trap Transfer Program might cause excessive consolidation of effort and allow monopolies to form. Individuals also commented that NMFS should only allow Federal permit holders who have already been qualified into an area to buy and sell traps in that area.

Response: Well over 80 percent of the United States' harvest of American lobster comes from lobster management areas lacking transferable trap programs, such as Area 1. As such, even in the unlikely event that trap effort becomes so consolidated in Areas 2, 3, and the Outer Cape that a few entities control all traps—an impossibility under the proposed plan—those entities would still not be able to so control the markets as to constitute a monopoly. Regardless, NMFS's proposed Trap Transfer Program would maintain current trap caps (800 traps in Area 2 and the Outer Cape Area and 1,945 in Area 3), to prevent excessive trap accumulation. In addition, the proposed rule would allow any Federal lobster permit holder, not just Federal lobster permit holders who qualify into the area, to buy allocated traps, thereby increasing the pool of potential buyers so that buying power would not be consolidated in a smaller number of area qualifiers.

Comment 12: One lobsterman stated at the DEIS public hearing in Chatham, Massachusetts, that he opposed allowing lobster management area non-qualifiers to gain access into a lobster management area by buying traps that were allocated to that management area. Other lobstermen, however, suggest that individuals not qualified into an area should be allowed to purchase area qualified traps.

Response: NMFS proposes to allow non-qualifiers to purchase qualified area lobster traps. Doing so will increase the pool of potential buyers and thus better facilitate the economic advantages to both buyer (e.g., access to fishing the area at a level appropriate to their business model) and seller (e.g., a larger pool of potential buyers). Allowing non-qualifiers to purchase qualified traps will also help younger entrants into the fishery participate at an economically-viable level (see response to Comment 10). Additionally, allowing non-qualifiers to purchase qualified traps will help offset impacts to individuals who might have fished the area in the past, but failed to qualify, or qualified at a lower trap allocation. The proposed rule would not go so far as to suggest that any individual—even those without federal lobster permits—could purchase qualified traps and fish in the area. Thus, the number of potential participants is greater than if limited solely to area qualifiers, but would be limited, nonetheless. Specifically, the total number of possible participants is limited to individuals with Federal lobster permits (there are presently about 3,152 Federal lobster permit holders). Additionally, geographical, economic, and regulatory considerations would prevent those participants from concentrating in one area. Requiring a purchaser to have a Federal lobster permit makes sense and provides some counter-balance: It restricts the number of purchasers to a finite pool and would allow NMFS to maintain management through its permits rather than shifting to a trap-based management paradigm. Further, limiting participation in the Trap Transfer Program to Federal lobster permit holders helps ensure the social and industry characteristics of the fishery insofar as purchasers would be existing lobster fishers rather than the general public, thereby ensuring that potential purchasers have at least some understanding of the fishery.

Comment 13: Some commenters expressed concern, both in writing and at NMFS's DEIS public hearings, that trap transferability programs sometimes allow latent effort to be activated.

Response: This proposed rule would not increase effort. Critical to understanding this point is using the current lobster fishery as a proper frame of reference. At present, any of the 3,152 existing Federal lobster permit holders can fish in Area 2, in the Outer Cape Area, or in both areas. Further, every one of those 3,152 permit holders could fish any number of traps up to the current trap cap of 800 traps. Under the proposed rule, however, the number of potential trap fishery participants is expected to drop from 3,152 to 207 in Area 2, and to 26 in the Outer Cape Area. NMFS knows that the number of permit holders actually fishing in Area 2 and the Outer Cape Area is far less than 3,152, but nevertheless, restricting access to approximately 233 permit holders (207 in Area 2 and 26 in the Outer Cape Area) based upon past fishing history represents a massive reduction in potential effort. Further, of the 233 permit holders expected to qualify, many, if not most, will be allocated less than the full 800-trap allocation, because many fishers did not fish with every possible trap during the qualifying years. Accordingly, not only will the number of Area 2 and Outer Cape Area fishers be reduced, but the number of traps that the area qualifiers can fish will also be reduced. Even those who receive the maximum 800-trap allocation will, at most, receive an allocation equal to, but not greater than, the number of traps currently allowed. In other words, whereas the present regulations allow anybody to fish up to 800 traps in these areas, the proposed regulations will allow only certain qualifiers to fish up to 800 traps, with many qualifiers allocated at trap levels below those allowed today. Again, this allocation would be tied to actual fishing history and, thus, result in a further reduction in potential effort.

Unfettered trap transferability, however, does have the theoretical potential to slightly increase actual effort as unused, latent traps in one business are sold to a different lobster business which could fish them more actively. But, that increase would only be relative to the administratively-created fishery occurring immediately after permit holders are qualified and allocated, not as compared to effort as it exists on the water today. Notably, the proposed rule's post-qualification/allocation characterization does not represent today's actual effort either: It represents actual effort as it existed in the early 2000's. Some of the qualifiers would receive an allocation greater than they now fish, others smaller than they now fish. When the parties transfer traps back and forth to get to their current-day business models, some presently latent traps might become active. But, many of these activated latent traps would be doing nothing more than replacing currently active traps that were not allocated during the allocation process—at most, a zero-sum gain. Nevertheless, the proposed rule offers a number of measures to balance against the activation of latent effort including: Permanently retiring 10 percent of all traps involved in transfers (sometimes referred to as a ''transfer tax'' or ''conservation tax''); requiring dually-permitted entities (those with both a state and Federal lobster permit) to reconcile inconsistent allocations by choosing the more restrictive number; and retaining trap caps on individual allocations. Accordingly, NMFS does not expect a great amount of latent effort to be activated through transfers, and asserts that its mitigation measures will offset any potential activation of latent effort.

Comment 14: Members of the public commented at the DEIS public hearings and in writing that latent traps should not be allowed to be transferred.

Response: Latent effort is potential effort. In the lobster fishery, latent effort represents the number of traps that could be fished, but that are not actually being fished at a specific point in time. For the purposes of this proposed rule, the specific point of time is the qualification/allocation time period set forth in the Commission's Lobster Plan. The Commission's Lobster Plan calculates trap allocation based upon a scientific regression formula to ensure that trap allocation correlates with fishing activity. Accordingly, every trap initially allocated can be considered active—or at least was active during the qualifying years chosen in the Commission's Lobster Plan. If, however, the commenters are suggesting that NMFS further restrict transfers of traps that have become latent since the qualification/allocation time period, then NMFS must point out the many problems with such a suggestion. First, although the commenters generally speak about latency, they have not provided a specific time period within which to determine latency. Latency is not static. It changes year-to-year, month-to-month, and even day-to-day. Traps that are active one month might become inactive the next and then reactivated the third month. Without a temporal context, latency cannot be determined with any degree of specificity. Second, even if a time period was given, there is no mandatory record-keeping to easily determine which traps were active at any given time and which traps were not. In other words, because it is seldom possible to precisely determine whether a trap is active or latent (or partially active/partially latent) it is extraordinarily difficult to craft a management program that allows only the transfer of active traps while preventing transfers of latent traps. Third, even were NMFS to somehow determine a trap's activity level in recent seasons, restricting its transfer would result in disconnects with the states because there is no restriction on the transfer of latent traps in the Commission's Lobster Plan. Ultimately, NMFS concludes that the Commission's Lobster Plan does a good job of preventing latent traps from being activated. To the extent that latency nevertheless exists, NMFS asserts that mitigation measures such as the 10 percent retirement of trap transfers will compensate for potential latent trap activation (see response to Comment 13).

Comment 15: One Outer Cape Area trap fisherman commented in a DEIS public hearing that if non-qualifiers could buy traps in the Outer Cape Area, then non-qualified gill-netters would buy small amounts of traps just to enter the area, but fish for lobster with gillnets.

Response: An individual's ability to fish for lobster is derived from his or her permit, not from the traps. The proposed rule would not change this. As a result, anybody fishing for lobster in the Outer Cape Area still must possess a Federal lobster permit. Therefore, the commenter's scenario would not occur under this proposed rule. That is, a Federal lobster permit holder would not need to buy traps as a ruse to get into the area because that permit holder could fish for lobster in the area with gillnets without a trap allocation if they already had a Federal lobster permit. If a person does not have a Federal lobster permit, only then would he or she not be allowed to participate in the proposed Trap Transfer Program to buy Outer Cape Area traps.

Comment 16: One industry group suggested that only traps that fished within the SNE area be transferrable within the SNE area.

Response: Areas 2, 3, and the Outer Cape all overlap multiple lobster stock areas. To further divide those lobster management areas by stock area would be akin to creating new sub-management areas, which is something the Commission's Lobster Plan neither does nor contemplates. Additionally,

existing documentation lacks sufficient clarity and precision to determine which stock area, within a given management area, a trap has been fished. Consequently, NMFS has determined that this suggestion cannot be implemented, and even if it were, it would likely result in inconsistencies with the Commission's Lobster Plan.

Comment 17: One organization representing Area 3 lobstermen recommended that Addendum XIII's 2,000-trap cap for Area 3 remain in place, although the commenters acknowledged that trap caps can and should be adjusted in later addenda. One lobsterman and his counsel opposed Addendum XIII's Area 3 2,000-trap cap as being too low and argued that upon allocating, and thus establishing, the total number of Area 3 traps in the qualification process, there is little reason to set individual trap caps on permits, especially a cap as low as 2,000 traps.

Response: At present, trap caps exist in every LCMA. In Area 2 and the Outer Cape Area, the cap is 800 traps. In Area 3, the highest trap cap is 1,945 traps. NMFS does not propose to change these limits in this proposed rule. First, most fishers have been fishing within the existing traps caps for over a decade. In May 2000, the Area 2 and Outer Cape Area trap caps were established at 800 traps and the Area 3 trap cap was set at 1,800 traps. After the initial Area 3 qualification and allocation process in 2003, the Area 3 trap cap jumped to 2,656 traps (very few permit holders qualified at that level), but was subject to a graduated yearly decrease so that no Area 3 fisher now deploys 2,000 traps, and most have an allocation far below that cap. Accordingly, failure to increase the cap in this rulemaking should not create any new impact on lobster businesses. Second, the mitigation provided by the Trap Transfer Program for lower allocations remains, regardless of the trap cap. Finally, and of great importance, the trap caps and their impacts on newer, more novel lobster management measures, such as controlled growth and banking, are being analyzed in great detail in draft addenda that have yet to be approved by the Commission's Lobster Board. Accordingly, it would be premature and imprudent to change trap caps in the Federal lobster regulations before having the opportunity to analyze and incorporate the proposals in the Commission's Addendum XVIII. NMFS intends to address the trap cap issue in a rulemaking that follows this present rulemaking.

Comment 18: One Area 2 lobsterman commented that he had a medical condition that drastically curtailed his lobster fishing activity during the qualifying years, and that he favored an appeal process that would allow him to qualify for access into Area 2, with a trap allocation reflecting his trap fishing history prior to his medical condition.

Response: NMFS's proposed rule contains provisions for hardship appeals in Area 2 based upon certain limited situations, such as situations in which medical incapacity or military service prevented a Federal lobster permit holder from fishing for lobster in 2001, 2002, and 2003. NMFS acknowledges the difficulties that such an appeal creates. Specifically, appeals based upon hardship can be extraordinarily subjective. What constitutes a hardship to one individual might not be so to another, and vice-versa. And short of hiring medical experts and cross-examination in a trial-type hearing—an expensive, resource intensive, and subjective process—it can be difficult to glean the applicant's state-of-mind to determine whether the matter truly prevented him or her from fishing. Accordingly, such appeals are difficult to manage by regulation and potentially introduce an exception that can threaten to engulf the rule. Lobster management, however, is a bottom to top process. In this case, the Area 2 lobster fishing industry, as well as the Commission's Lobster Board, decided after lengthy public input and debate that a limited medical hardship appeal was appropriate for Area 2. Further, Rhode Island allowed this type of appeal in its qualification process and found it manageable and just. In proposing a hardship appeal provision here, NMFS gives weight to the lobster management process, and the experience of the industry and Board in making the proposal and finds the rationale for their appeal to be reasonable.

Comment 19: An Area 2 commenter suggested that NMFS provide for a medical appeal that mirrored Rhode Island's medical appeal so that there would not be a discrepancy between his state and Federal trap allocation. He claimed that he fished state and Federal waters as a single entity and that a trap discrepancy between his state and Federal allocations would disrupt his business.

Response: Commission Addenda VII (2005) and XII (2009) both establish the premise that a single fishing operation will be considered to have developed a single indivisible fishing history even if that history was established under jointly held state and Federal fishing permits. NMFS's DEIS further acknowledged the importance of this premise and discussed the problems created by regulatory disconnects if a state and NMFS were to make inconsistent qualification and allocation decisions on that single fishing history. As a result, NMFS's proposed rule attempts to align itself with the regulatory processes already established by the states, including the appeals process set forth by Rhode Island, to the greatest extent practicable, acknowledging, of course, the difficulties in creating a Federal regulation that is consistent with state regulations that are themselves not always completely aligned.

Comment 20: Members of the public, lobstermen, the Massachusetts Lobstermen's Association, state and Federal legislators, as well as the Massachusetts Division of Marine Fisheries were concerned about unavoidable regulatory disconnects between NMFS and the states and urged NMFS to address these discrepancies in an appeals process or by grandfathering in earlier trap transfers.

Response: NMFS analyzed this issue in detail in the DEIS and shares these concerns. For this reason, NMFS introduces a Director's Appeal in this proposed rule. The Director's Appeal would allow states to petition NMFS for comparable trap allocations on behalf of Area 2 and Outer Cape Area applicants denied by NMFS. The appeal would be available only to Area 2 and Outer Cape Area participants for whom a state has already granted access. The Director's Appeal would allow more effort to qualify and enter the EEZ than would otherwise occur. NMFS, however, does not expect this potential additional effort to negatively impact the fishery. First, the number of appeals is limited to individuals who have already qualified under their state permit. These individuals, therefore, are already exerting fishing pressure on the lobster stock, albeit limited to state waters. Second, the DEIS analysis suggests strong correlation between state qualifiers and potential Federal qualifiers so, although some disconnects will likely occur, the DEIS predicts that the number will be relatively low. Finally, even if NMFS encounters a greater-than-predicted number of Director's Appeals, NMFS nevertheless concludes that synchronicity is so crucial as to be the overriding factor in proposing the appeal. To the extent that the extra qualified effort becomes a problem, which given the scale of the fishery seems unlikely, this effort can be further reduced in future Commission addenda rule recommendations.

Comment 21: Members of the public, lobstermen, the Massachusetts

Lobstermen's Association, state and Federal legislators, as well as the Massachusetts Division of Marine Fisheries, all indicate that Massachusetts allowed permit holders to transfer traps in the Outer Cape Area. As a result, even if NMFS were to allocate traps consistent with a state's initial allocation, the initial Federal allocation might not match the current state trap allocation because of the state allocation transfers that have subsequently occurred. The commenters recommend that NMFS grandfather in transactions that have already occurred, or adopt some other process to ensure that businesses with state and Federal permits have consistent allocations.

Response: NMFS agrees that the potential for disparate allocations amongst dually-licensed permit holders exists in any dually-administered allocation program. As a result, this proposed rule offers numerous safeguards without having to grandfather in earlier transactions. First, as discussed in response to Comment 20, NMFS's DEIS analysis suggests that the number of disconnects will be low. More recent Massachusetts Division of Marine Fisheries information confirms the DEIS conclusion and indicates that Massachusetts only allowed a negligible number of dually-permitted trap transfers (less than 1,000 traps) before freezing further transactions. Accordingly, NMFS expects that its proposed Director's Appeal will resolve most, if not all, of the problems. Additionally, although individuals with inconsistent allocations will not be forced to relinquish a state or Federal allocation, they will not be allowed to exacerbate the inconsistency by participating in the Federal Trap Transfer Program and transferring portions of the disparate trap allocations.

Comment 22: Massachusetts Division of Marine Fisheries, the Commission and members of the fishing industry commented in support of the Outer Cape Area January 15th to March 15th area closure.

Response: NMFS proposes to adopt the Commission's recommended closure and prohibit lobster traps in the Federal waters of the Outer Cape Area from January 15th to March 15th of each fishing year. There are numerous benefits to such a closure. Not only would it provide the lobster resource with a 2-month respite from fishing pressure, but the closure would also provide a bright-line enforcement standard: A 2-month period where no lobster trap can be legally set in the area. Thus, any traps encountered in the area during this time period would be either illegal or abandoned, and, in either case, can be easily removed by law enforcement agents. Removing illegal gear is important because it removes excess gear, which benefits lobster by decreasing effort on the resource. It also makes cheating (fishing a number of traps in excess of the allowable trap limit) harder to do, which benefits the vast majority of lobster fishers who abide by the regulations, and lends credence to the overall management process. Removing abandoned gear (also called ''ghost gear'') would benefit the lobster resource because abandoned gear still traps, and potentially kills, lobster. NMFS notes that Massachusetts currently is proposing to alter the dates of this 2-month winter closure to February 1st through March 31st. Ultimately, NMFS considers it more important that the involved state and Federal governments coordinate the dates of their 2-month Outer Cape Area closure, than for NMFS to stick to its presently proposed January 15th to March 15th timeframe. If Massachusetts implements this proposed law, then NMFS will consider altering its proposed 2-month closure to correspond with the state law.

Comment 23: The Marine Mammal Commission commented that NMFS needs to be mindful of its responsibilities to consult under section 7 of the Endangered Species Act.

Response: NMFS is aware of its responsibilities under the Endangered Species Act and is in the process of consulting with its Protected Resources Division on this matter.

Comment 24: The Marine Mammal Commission was concerned that the proposed measures could alter the level and distribution of effort, particularly in Cape Cod Bay and the Great South Channel, which could increase entanglement risks for whales.

Response: As a preliminary matter, the proposed measures are specific to Area 2, Area 3, and the Outer Cape Area. The measures are not expected to increase lobster fishing effort in Cape Cod Bay, which is in Area 1 and to which lobster fishing access was limited by a final rule dated June 1, 2012 (77 FR 32420). As for the Great South Channel, this proposed rule has the potential to decrease whale entanglement. First, the proposed rule should not expand effort, but decrease effort, because it would limit lobster fishing access in Area 2 and the Outer Cape Area to approximately 233 permit holders (207 in Area 2 and 26 in the Outer Cape Area), as opposed to all 3,152 Federal lobster permit holders who can currently fish in Area 2 and the Outer Cape Area—including portions of the Great South Channel. Thus, the proposed rule would restrict effort shift because traps would be restricted to being fished only in those areas in which they have fished in the past. Second, the proposed rule would allow for a more precise quantification of fishing effort as it would allocate a finite number of lobster traps, which would allow managers to better manage the lobster resource in each area. Third, although an unfettered trap transferability program might have the potential to increase effort to the extent latent traps become transferred and activated, the proposed rule offers measures to minimize this risk. For example, NMFS does not propose to give all qualifiers a flat 800-trap allocation (which is the number of traps permit holders can currently fish). Instead, NMFS would establish their initial allocation at the level of their demonstrated fishing history, thus decreasing the prospects that latent traps will become activated through the allocation process. In addition, the proposed Trap Transfer Program has set trap caps and a 10 percent conservation tax per trap transfer. Finally, NMFS proposes that all lobster traps be removed from the Outer Cape Area—including involved areas of the Great South Channel—for a 2-month period in late winter. NMFS discusses these issues in greater detail in the DEIS and further discusses latency issues in its responses to Comments 7, 13, and 14.

Comment 25: The Marine Mammal Commission recommended that NMFS require Federal lobster permit holders to provide data on their fishing practices to help evaluate the risk of interactions with whales and the effectiveness of related management actions.

Response: Although the nature of the request is vague, NMFS interprets the intent of the comment to suggest that additional data would help whale conservation and lobster resource management. NMFS generally agrees, but notes that the Commission's Lobster Board has struggled with this issue and has not yet reached consensus on how to best accomplish data needs in the fishery. The Board took an important step in Addendum X, which mandated lobster dealer reporting, and which NMFS implemented in 2009 (74 FR 37530). NMFS considers it important for the Lobster Board to provide direction so that all the managing states and Federal governments are operating in synergy. The Lobster Board did not recommend further lobster reporting in this action and, as a result, the request of the commenter is beyond the scope of this rulemaking. Nevertheless, better

data and understanding of the fishery is expected to result from this action. Specifically, this action would allow Federal managers to more precisely know actual fishing effort in Area 2 and the Outer Cape Area, which should aid in both the management of lobster and conservation of whales. This action also requires the creation of a centralized lobster trap tracking system that might also provide better data and understanding of the fishery. The significance of the lobster trap tracking system is discussed in greater detail earlier in this proposed rule in the section entitled: *ITT Program—NMFS's Response to Commission Recommendations and Proposed ITT Rule.*

Comment 26: The Environmental Protection Agency noted that the DEIS discussed the significance of water temperature on lobster and suggested that the Final Environmental Impact Statement contain the most current science on how temperature affects lobster.

Response: NMFS intends for the Final Environmental Impact Statement to contain the best available scientific information.

Comment 27: One commentator suggested that leasing of traps be allowed in addition to being sold during the trap transferability process, because doing so would provide industry with greater flexibility.

Response: NMFS does not propose to add leasing traps to its Trap Transfer Program. The Commission did not recommend leasing when it proposed its trap transferability program and to do so without the Commission and states also doing so would increase the potential for disconnects amongst the states, Federal government, and industry.

Classification

This proposed rule has been determined to be not significant for the purposes of Executive Order (E.O.) 12866.

This proposed rule does not contain policies with federalism implications as defined in E.O. 13132. The proposed measures are based upon the Lobster ISFMP that was created by and is overseen by the states. The proposed measures are a result of multiple addenda, which were approved by the states, recommended by the states through the Commission for Federal adoption, and are in place at the state level. Consequently, NMFS has consulted with the states in the creation of the ISFMP, which makes recommendations for Federal action. Additionally, these proposed measures would not pre-empt state law and would do nothing to directly regulate the states.

This proposed rule contains a collection of information requirement subject to review and approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). A PRA analysis, including a revised Form 83i and supporting statement, has been submitted to OMB for approval. The PRA analysis evaluates the burden on Federal lobster permit holders resulting from the application and appeals process, as well as the Trap Transfer Program.

Burden on the Public

Prior to the start of the eligibility and allocation application process, NMFS will contact all Federal lobster permit holders and inform them of whether or not the agency has information on hand to demonstrate that a permit meets the eligibility requirements based upon the review of data provided by the states.

There are five types of respondents characterized in the PRA analysis. Group 1 applicants are those for whom NMFS has data on hand to show that their permits meet the eligibility criteria for one or both of the Outer Cape Area and Area 2. These permit holders would still need to apply by submitting an application form to NMFS agreeing with the NMFS assessment of their eligibility based on the state data. Group 2 applicants are the subset of Group 1 pre-qualifiers who do not agree with the NMFS pre-determination of the areas they are eligible for and/or the corresponding trap allocations. These applicants would be required to submit the application form, but would also need to provide additional documentation to support their disagreement with NMFS's assessment of their permits' eligibility. Group 3 applicants are those Federal lobster permit holders for whom there are no state data available to show that their permits meet the eligibility criteria for either Area 2 or the Outer Cape Area and who, consequently, have no trap allocation for either areas based on NMFS's review of the state-supplied data. Permit holders in this group may still apply for eligibility, but must submit, along with their application forms, documentation to support their claim of eligibility and trap allocation for the relevant areas. Group 4 are those who apply for access to either Area 2 and/or the Outer Cape Area, are deemed ineligible (a subset of Groups 2 and 3), and appeal the decision based on a military, medical, or technical issue. Group 5 consists of those who fall under the Director's Appeal. The Director's Appeal process was established to address those Federal lobster permit holders who were qualified into either Area 2 and or the Outer Cape Area by their state, but their eligibility is not based on the qualification criteria set forth by the Commission's Lobster Plan. The Director's Appeal allows a state's fisheries director to appeal on behalf of such permit holders and advocate for their qualification to avoid disconnects that could occur if they were qualified by their state, but not by the Federal Government.

The PRA requires NMFS to estimate the individual and overall time and economic cost burdens to the affected public and the Federal Government. To apply, Group 1 applicants would need only to check off the area(s) they are seeking access to on an application form, sign the form, and submit it to NMFS for review. The burden for each applicant is estimated at 2 minutes. We expect about 202 applicants from this category, totaling 6.7 hours of burden for all Group 1 applicants combined. Each Group 1 application is expected to cost the applicant $0.95 for postage, paper, and envelopes, totaling about $192 for all 202 Group 1 applicants.

Because they are not pre-qualified, the application process for Group 2 and 3 applicants is expected to take 22 minutes: 2 minutes to complete and sign the application form; and 20 minutes to locate documentation to support the eligibility criteria. We expect about 31 Group 2 applicants and 79 Group 3 applicants. Consequently, the overall burden for all Group 2 and Group 3 applicants is estimated at 11.4 hours, and 29 hours, respectively. Group 2 and 3 applications are expected to cost each applicant about $1.75 for paper, postage, and envelopes, totaling about $193 for all 110 Group 2 and 3 applicants.

Group 4 applicants, those whose appeal a NMFS decision to deny their application, would require about 30 minutes to prepare and submit an appeal. Twenty-one appellants are expected from this group, totaling 11 hours of time for all 21 appellants to complete the appeal. The cost to each appellant to prepare and submit an appeal is $4.42, with a total of about $93 for all 21 Group 4 appeals.

Group 5 appellants, those who appeal under a Director's Appeal, would require 20 minutes of time to complete and file the appeal. With 40 expected appellants, the total burden for this group is estimated at 13 hours. Each Director's Appeal is estimated to cost each appellant about $1.90, totaling $76 for all 40 permit holders expected through the Director's Appeal.

Once the area eligibility decisions have been made and a specified

majority of the Area 2 and Outer Cape Area permits have been qualified and allocated traps, a trap transferability program will begin, allowing all Federal lobster permit holders, regardless of whether their permit qualified for the Area 2, Area 3, or Outer Cape Area trap fisheries, to purchase lobster trap allocations and gain access to these exclusive areas. Permit holders whose permits qualified for these areas may sell all or some of their trap allocation to other Federal lobster permit holders, and also may buy additional traps for these areas, up to an area-specific trap limit. Trap transfers for all interested permit holders would be restricted to a specified period. For each transaction, a buyer and a seller must complete a trap transfer form indicating the number of traps to be transferred, the permit information for each affected vessel, the amount of traps to account for the conservation tax, and other information needed to fully process and account for the transaction.

Prior to the implementation of the trap transfer program, a joint state/Federal database is expected to be on line to allow state agencies and NMFS to track the transfers by their respective permit holders—this is especially critical for tracking transfers between dual permit holders (those holding both a state and Federal lobster permit), because all agencies must have current and consistent records of a permit holder's trap allocation for tracking and enforcement. NMFS anticipates that such a system would likely allow permit holders to transfer traps using a Web site, which would feed into the joint state/Federal database as well as the relevant in-house state and Federal permit databases to facilitate submission and tracking. Regardless of the on-line option, we may accept hard copy trap transfer forms, depending upon the operational status of the inter-agency centralized trap transfer data base at the time the transfer program commences.

We estimate that the time needed for a permit holder to submit a transfer transaction online is the same amount of time as filling out and submitting a hard copy, but the costs of an electronic submission could be $0.00, because those choosing that option may already have access to a computer and the Internet. Nevertheless, because this is a new program and we have no exact method for determining the percentage of permit holders who would conduct their trap transfer transactions on-line we will assume, for the purposes of public burden estimation, that all participants will conduct their transactions with hard-copy submissions. We estimate that it would take 10 minutes to complete a trap transfer request. We expect that each year, about 432 Federal lobster permit holders will apply to buy or sell traps. Each transfer transaction requires two permit holders: A buyer and a seller. Therefore, the number of expected participants is twice the number of expected transactions. Accordingly, about 216 trap transfer applications are expected, with a total permit holder burden of 36 hours. Costs for each transfer transaction are the combined costs of paper, envelopes, and postage, calculated at $5.62 per transfer application, totaling $1,214 for all 216 transfer requests.

Total cost to the affected permit holders for all applications, appeals, and the first year of the trap transfer program are the combined costs of all these categories, totaling about $1,768.

Public comment is sought regarding whether this proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the burden estimate; ways to enhance the quality, utility, and clarity of the information to be collected; and ways to minimize the burden of the collection of information, including though the use of automated collection techniques or other forms of information technology. Send comments on these or any other aspects of the collection of information to the Sustainable Fisheries Division at the **ADDRESSES** above, and by email to *OIRA_Submission@omb.eop.gov* or fax to (202) 395–7285.

Notwithstanding any other provision of the law, no person is required to respond to, and no person shall be subject to penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB control number.

Economic Impact of the Proposed Rule on Small Entities

1. Regulatory Flexibility Act: Background

NMFS prepared an Initial Regulatory Flexibility Analysis (IRFA) as required by section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact this proposed rule, if adopted, would have on small entities. Such an analysis requires an initial finding that (1) small entities are involved; and (2) that economic impacts would result. Both factors occur here.

NMFS prepared this IRFA in tandem with the DEIS, which was made available in 2010. The DEIS and IRFA are based on 2007 data, which was the most recent and best available when these analyses were initiated. All lobster permit holders are being considered small business entities for the purposes of the analysis. The Small Business Administration's size standard for commercial fishing (NAICS 1141) is $4 million in gross sales. The proposed action would potentially affect any fishing vessel using trap gear that holds a Federal lobster permit. During 2007, a total of 3,287 Federal lobster permits were issued. Of these permits, 699 were issued only a non-trap gear permit, 2,168 were issued only a trap-gear permit, and 420 held both a trap and a non-trap gear permit. According to dealer records, no single lobster vessel exceeded $4 million in gross sales. Some individuals own multiple operating units, so it is possible that affiliated vessels would be classified as a large entity under the SBA size standard. However, the required ownership documentation submitted with the permit application is not adequate to reliably identify affiliated ownership. Therefore, all operating units in the commercial lobster fishery are considered small entities for purposes of analysis.

The second required finding—that economic impacts would result—also occurs here. In fact, a primary reason in proposing this rule is to have an economic impact, i.e., to establish regulations that ''…promote economic efficiency within the fishery…'' (see Supplementary Information— Purpose and Need for Management). The DEIS analysis of preferred and non-preferred alternatives and this proposed rule's discussion of proposed and rejected actions are largely an analysis of the economic impacts of the proposed measures and their alternatives on small business entities. This section is only a summary of the full impact analysis NMFS completed for this action. Although this section attempts to provide a broad sense of the IRFA, NMFS advises the public to review its DEIS as well as earlier sections of this proposed rule for a more detailed understanding of the economic impacts.

2. Regulatory Flexibility Act—Overview of Economic Impacts Analysis

The economic impacts of the proposed limited entry program for the Outer Cape Area and Area 2 cannot be quantified with any meaningful precision. The economic viability of a lobster business is not simply dependent on the amount of lobster harvested, but is also dependent on the cost of resources expended to harvest

lobster (such as fuel, bait, boat mortgages, etc.). Information about the costs is not collected and, therefore, is not available for this analysis. Even if the information were available, human factors, such as skill of the captain, decisions on when and where to fish, and when to bring the harvest to market so impact lobster economics that quantification would still not be possible. Nevertheless, a qualitative analysis of potential economic impacts is both possible and helpful to better understand the impacts of the proposed rule and its alternatives.

In the Outer Cape Area and Area 2, the proposed action would implement a limited access program with individual trap allocations. This action would mean that any Federal permit holder who did not qualify for limited access would not be able to set traps in either area now or in the future. Based on preliminary estimates, a total of 207 Federal lobster trap vessels would qualify for Area 2 and 26 Federal lobster trap vessels would qualify for limited access in the Outer Cape Area. Conceptually, then, more than 2,000 Federal lobster permit holders would not qualify. However, the majority of these non-qualifiers either do not currently participate in any lobster trap fishery, or they set traps in other LCMAs.

Past Federal lobster regulations allowed individuals to select any lobster management area on their annual permit renewal. For a variety of reasons, some vessel owners elect multiple areas, yet have no history or intent of actually setting traps in all of them. Election of an LCMA may be thought of as representing an option to set traps in an area, whereas the purchase of trap tags may reflect an indication of the intent to actually fish there. For example, during 2007, a total of 431 permit holders elected Area 2 on their permit application and 170 elected the Outer Cape Area. Only 38 of the 170 vessels electing the Outer Cape Area in 2007 purchased Outer Cape Area trap tags, while in Area 2, only 182 of 431 vessels purchased Area 2 trap tags. For purposes of further discussion, vessels that have elected to fish in either Area 2 or the Outer Cape Area will be considered participating vessels.

As noted above, in 2007, there were 182 participating businesses engaged in the Area 2 trap fishery, whereas the proposed action would qualify a total of 207 permitted vessels. Whether all of the participating vessels would be included in the 207 vessels that would qualify for limited access in Area 2 is uncertain. Nevertheless, the number of qualifying vessels under the proposed action would likely exceed the number of currently participating vessels. By contrast, the number of qualifying vessels in the Outer Cape Area would be less than the number of currently participating vessels. Specifically, participating vessels from both Rhode Island (nine) and New Jersey (three) might no longer be allowed to participate in the Outer Cape Area lobster trap fishery. Note that the actual level of participation by these non-qualified vessels is uncertain because, in the absence of mandatory reporting, we cannot verify whether or not any traps were actually fished in the area, which also means that the economic impacts on any non-qualified participating vessels cannot be reliably estimated.

In the absence of action (i.e., the no-action alternative identified in the DEIS) a shift in effort could likely occur into Area 2 and the Outer Cape Area because the two areas would be the only remaining open-access lobster management areas. In other words, under the no-action alternative, any Federal lobster permit holder could fish in those two areas, including permit holders who have no trap fishing history during the qualification period, and those excluded from fishing in nearby areas. In such a scenario, the most likely economic impact would be a dilution in profitability for current and future participants in the lobster fishery. Increasing the number of participating vessels and traps fished in either area may result in higher landings overall, but unless landings linearly increase with traps fished, landings, and average gross stock per vessel would be likely to go down. In effect, limited access would insulate the majority of current participating vessels from the external diseconomies that typify open access fisheries.

NMFS's proposed qualification process should aid small lobster businesses by streamlining what might otherwise be a cumbersome application process. NMFS proposes to allow applicants to provide their state qualification and allocation decision as proof of what their Federal allocation should be. In contrast, in its earlier limited access programs for Areas 3, 4, and 5, NMFS required that all applicants provide documentation, including an affidavit, which was a time-consuming and relatively burdensome, albeit necessary, process. Here, NMFS reviewed the applicable regulations for the involved states and determined that the state criteria was substantially identical to the proposed Federal criteria, which is not surprising because the Commission proposed that the states and NMFS implement compatible regulations based upon Commission recommended addenda. Thus, NMFS will accept state allocation information as the best evidence of its decision unless NMFS had reason to think the underlying state decision was incorrect.

NMFS proposes a limited number of appeals to its Area 2 and Outer Cape Area limited access programs. These appeals have economic benefit to small lobster businesses because they afford an opportunity for lobster businesses to qualify and receive a trap allocation they otherwise would be denied. NMFS considered the alternative of having no appeals. Having no appeals would likely result in a smaller number of qualifiers, which could result in some economic advantage to existing qualifiers in that they would receive a proportionately greater share of access to the resource. The DEIS, however, predicts that the number of appeals will be low, and as such, excluding appeals would likely result in little measurable economic advantage to the other qualifiers. In contrast, failure to include appeals could result in negative economic impacts. Certainly, denying access to a permit holder who might otherwise qualify through an appeal would have a direct negative impact to that permit holder. Further still, the states and Commission recommended that appeals be implemented in their addenda. NMFS's failure to similarly include appeals would result in regulatory disconnects. The DEIS discusses in further detail the negative impacts that a disjointed regulatory program would have on small businesses, government managers, and the lobster resource.

As noted previously, the proposed action would create individual trap allocations and would implement a transferable trap program. Conceptually, initial allocations would preserve the relative competitive position among qualifying lobster trap fishing businesses, but transferability would provide regulated lobster trap vessels with the flexibility to adjust trap allocations as economic conditions and business planning warrant. This program would be an overall economic benefit to lobster businesses. Failure to implement such a transferable trap program (e.g., by selecting the no-action alternative identified in the DEIS) would likely result in negative economic impacts. First, non-qualifiers would be excluded from future trap access into the areas, while qualifiers with low allocations might lack sufficient traps to operate profitably according to their selected business model. Second, qualifiers with

sufficient allocation would lose the opportunity to derive profit from the incremental sale of traps as they scale down and retire their business. Third, failure to implement a transferable trap program would create regulatory disconnects between NMFS, the states, and Commission, given that some states have already implemented a trap transfer program, and because the Commission is relying on trap transferability as a foundational element to its effort reduction measures identified in Addendum XVIII.

The proposed Trap Transfer Program differs from that of the Commission's recommended alternative in that once initial qualifications for trap allocations have been made in each LCMA, the ability to purchase traps to fish in the area under the proposed Trap Transfer Program would not be limited to only individuals that qualified for limited entry. This program feature affords small lobster trap fishing businesses the flexibility to scale their businesses up or down, and acquire and set traps in any LCMA in which trap allocations have been established and trap transferability has been approved (presently, Areas 2, 3, and the Outer Cape Area). This feature has several economic advantages. Without this feature, under the no-action alternative, the only way a non-qualified Federal lobster permit holder could fish in Areas 2, 3, and/or the Outer Cape Area, would be by purchasing someone else's qualifying vessel and traps. The proposed action would, in effect, implement a single Trap Transfer Program for Areas 2, 3, and the Outer Cape Area. This feature would not only reduce the administrative costs of running the Trap Transfer Program, but would also simplify the Program for potential lobster trap fishery participants. However, while the purchase of less than a full complement of transferable traps would be allowed, the ability to fish traps would be impacted by enforcement of the Most Restrictive Rule set forth in § 697.3 and § 697.4. In cases where a trap allocation in a specific LCMA would be low, lobster fishing businesses electing to fish/utilize those traps in that area would be bound or capped to that low allocation of traps for all LCMAs they intend to fish in for the entire fishing year.

List of Subjects in 50 CFR Part 697

Fisheries, fishing.

Dated: June 4, 2013.

Alan D. Risenhoover,

Director, Office of Sustainable Fisheries, performing the functions and duties of the Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 697 is proposed to be amended as follows:

PART 697—ATLANTIC COASTAL FISHERIES COOPERATIVE MANAGEMENT

■ 1. The authority citation for part 697 continues to read as follows:

Authority: 16 U.S.C. 5101 *et seq.*

■ 2. In § 697.4, remove paragraphs (a)(7)(ix) through (a)(7)(xi), and revise paragraphs (a)(7)(ii), (a)(7)(vii) and (a)(7)(viii) to read as follows:

§ 697.4 Vessel permits and trap tags.

(a) * * *

(7) * * *

(ii) Each owner of a fishing vessel that fishes with traps capable of catching lobster must declare to NMFS in his/her annual application for permit renewal which management areas, as described in § 697.18, the vessel will fish in for lobster with trap gear during that fishing season. The ability to declare into Lobster Conservation Management Areas 1, 2, 3, 4, 5, and/or the Outer Cape Management Area, however, will be first contingent upon a one-time initial qualification, as set forth in paragraphs (a)(7)(vi) through (a)(7)(viii) of this section.

* * * * *

(vii) Participation requirements for EEZ Nearshore Outer Cape Area (Outer Cape Area). To fish for lobster with traps in the EEZ portion of the Outer Cape Area, a Federal lobster permit holder must apply for access in an application to the Regional Administrator. The application process is set forth as follows:

(A) *Qualification criteria.* To initially qualify into the EEZ portion of the Outer Cape Area, the applicant must establish with documentary proof the following:

(*1*) That the applicant possesses a current Federal lobster permit;

(*2*) That the applicant landed lobster caught in traps from the Outer Cape Area in either 1999, 2000, or 2001. Whichever year used shall be considered the qualifying year for the purposes of establishing the applicant's Outer Cape Area trap allocation;

(B) *Trap allocation criteria.* To receive a trap allocation for the EEZ portion of the Outer Cape Area, the qualified applicant must also establish with documentary proof the following:

(*1*) The number of lobster traps fished by the qualifying vessel in 2000, 2001, and 2002; and

(*2*) The total pounds of lobster landed in 2000, 2001, and 2002.

(C) *Trap allocation formula.* The Regional Administrator shall allocate traps for use in the Outer Cape Area based upon the applicant's highest level of Effective Traps Fished during the qualifying year. Effective Traps Fished shall be the lower value of the maximum number of traps reported fished for that qualifying year compared to the predicted number of traps that is required to catch the reported poundage of lobsters for that year as set forth in the Commission's allocation formula identified in Addendum XIII to Amendment 3 of the Commission's Interstate Fishery Management Plan for American Lobster.

(D) *Documentary proof.* To satisfy the Outer Cape Area Qualification and Trap Allocation Criteria set forth in paragraphs (a)(7)(vii)(A) and (B) of this section, the applicants will be limited to the following documentary proof:

(*1*) As proof of a valid Federal lobster permit, the applicant must provide a copy of the vessel's current Federal lobster permit. The potential qualifier may, in lieu of providing a copy, provide NMFS with such data that would allow NMFS to identify the Federal lobster permit in its data base, which would at a minimum include: The applicant's name and address, vessel name and permit number.

(*2*) As proof of traps fished the Outer Cape Area and lobsters landed from the Outer Cape Area in either 2000, 2001, or 2002, the applicant must provide the documentation reported to the state of the traps fished and lobsters landed during any of those years as follows:

(*i*) *State records.* An applicant must provide documentation of his or her state reported traps fished and lobster landings in 2000, 2001, or 2002. The Regional Administrator shall presume that the permit holder was truthful and accurate when reporting to his or her state the traps fished and lobster landed in 2000, 2001, and 2002 and that the state records of such are the best evidence of traps fished and lobster landed during those years.

(*ii*) *State decision.* An applicant may provide their state's qualification and allocation decision to satisfy the documentary requirements of this section. The Regional Administrator shall accept a state's qualification and allocation decision as prima facie evidence of the Federal qualification and allocation decision. The Regional Administrator shall presume that the state decision is appropriate, but that

presumption is rebuttable and the Regional Administrator may choose to disallow the use of the state decision if the state decision was incorrect or based on factors other than those set forth in this section. This state decision may include not only the initial state qualification and allocation decision, but may also incorporate state trap transfer decisions that the state allowed since the time of the initial allocation decision.

(*iii*) *States lacking reporting.* An applicant may provide Federal vessel trip reports, dealer records or captain's logbook as documentation in lieu of state records if the applicant can establish by clear and convincing evidence that the involved state did not require the permit holder to report traps or landings during 2000, 2001, or 2002.

(E) *Application period.* Applicants will have 180 days to submit an application. The time period for submitting an application for access to the EEZ portion of the Outer Cape Area begins on the date 30 days after publication of this final rule (application period start date) and ends 210 days after the publication of the final rule. Failure to apply for Outer Cape Management Area access by that date shall be considered a waiver of any future claim for trap fishery access into the Outer Cape Area.

(F) *Appeal of denial of permit.* Any applicant having first applied for initial qualification into the Outer Cape Area trap fishery pursuant to this section, but having been denied access or allocation may appeal to the Regional Administrator within 45 days of the date indicated on the notice of denial. Any such appeal must be in writing. Appeals may be submitted in the following two situations:

(*1*) *Clerical error.* The grounds for administrative appeal shall be that the Regional Administrator erred clerically in concluding that the vessel did not meet the criteria in paragraph (a)(7)(vii) of this section. Errors arising from oversight or omission such as ministerial, mathematical, or typographical mistakes would form the basis of such an appeal. Alleged errors in substance or judgment do not form a sufficient basis of appeal under this paragraph. The appeal must set forth the basis for the applicant's belief that the Regional Administrator's decision was made in error. If the appealing applicant does not clearly and convincingly prove that an error occurred, the appeal must be denied.

(*2*) *Director's appeal.* A state's marine fisheries agency may appeal on behalf of one of its state permit holders. The only grounds for a Director's Appeal shall be that the Regional Administrator's decision on a dual permit holder's Federal permit has created a detrimental incongruence with the state's earlier decision on that permit holder's state permit. In order to pursue a Director's Appeal, the state must establish the following by a preponderance of the evidence:

(*i*) *Proof of an incongruence.* The state must establish that the individual has a state lobster permit, which the state has qualified for access with traps into the Outer Cape Area, as well as a Federal lobster permit, which the Regional Administrator has denied access or restricted the permit's trap allocation into the Outer Cape Area. The state must establish that the incongruent permits were linked during the year or years used in the initial application such that the fishing history used in Federal and state permit decisions was the same.

(*ii*) *Proof of detriment.* The state must provide a letter supporting the granting of trap access for the Federal permit holder. In the support letter, the state must explain how the incongruence in this instance is detrimental to the Outer Cape Area lobster fishery and why granting the appeal is, on balance, in the best interests of the fishery overall. A showing of detriment to the individual permit holder is not grounds for this appeal and will not be considered relevant to the decision.

(G) *Appellate timing and review.* All appeals must be submitted to the Regional Administrator in writing and reviewed as follows:

(*1*) *Clerical appeals timing.* Applicants must submit Clerical Appeals no later than 45 days after the date on the NMFS Notice of Denial of the Initial Qualification Application. NMFS shall consider the appeal's postmark date as constituting the submission date for the purposes of determining timing. Failure to register an appeal within 45 days of the date of the Notice of Denial will preclude any further appeal. The appellant may notify the Regional Administrator in writing of his or her intent to appeal within the 45 days and request a time extension to procure the necessary documentation. Time extensions shall be limited to 30 days and shall be calculated as extending 30 days beyond the initial 45-day period that begins on the original date on the Notice of Denial. Appeals submitted beyond the deadlines stated herein will not be accepted.

(*2*) *Director's appeals timing.* State Directors must submit Director's Appeals on behalf of their constituents no later than 180 days after the date of the NMFS Notice of Denial of the Initial Qualification Application. NMFS shall consider the appeal's postmark date as constituting the submission date for the purposes of determining timing. Failure to register an appeal within 180 days of the date of the Notice of Denial will preclude any further appeal. The Director may notify the Regional Administrator in writing of his or her intent to appeal within the 180 days and request a time extension to procure the necessary documentation. Time extensions shall be limited to 30 days and shall be calculated as extending 30 days beyond the initial 180-day period that begins on the original date on the Notice of Denial. Appeals submitted beyond the deadline will not be accepted.

(*3*) *Agency response.* Upon receipt of a complete written appeal with supporting documentation in the time frame allowable, the Regional Administrator will then appoint an appeals officer who will review the appellate documentation. After completing a review of the appeal, the appeals officer will make findings and a recommendation, which shall be advisory only, to the Regional Administrator, who shall make the final agency decision whether to qualify the applicant.

(H) *Status of vessels pending appeal.* The Regional Administrator may authorize a vessel to fish with traps in the Outer Cape Area during an appeal. The Regional Administrator may do so by issuing a letter authorizing the appellant to fish up to 800 traps in the Outer Cape Area during the pendency of the appeal. The Regional Administrator's letter must be present onboard the vessel while it is engaged in such fishing in order for the vessel to be authorized. If the appeal is ultimately denied, the Regional Administrator's letter authorizing fishing during the appeal will become invalid 5 days after receipt of the notice of appellate denial, or 15 days after the date on the notice of appellate denial, whichever occurs first.

(viii) *Participation requirements for EEZ nearshore lobster management area 2 (Area 2).* To fish for lobster with traps in the EEZ portion of Area 2, a Federal lobster permit holder must apply for access in an application to the Regional Administrator. The application process is set forth as follows:

(A) *Qualification criteria.* To initially qualify into the EEZ portion of Area 2, the applicant must establish with documentary proof the following:

(*1*) That the applicant possesses a current Federal lobster permit;

(*2*) That the applicant landed lobster caught in traps from the Area 2 in either

2001, 2002, or 2003. Whichever year used shall be considered the qualifying year for the purposes of establishing the applicant's Area 2 trap allocation;

(B) *Trap allocation criteria.* To receive a trap allocation for the EEZ portion of Area 2, the qualified applicant must also establish with documentary proof the following:

(*1*) The number of lobster traps fished by the qualifying vessel in the qualifying year; and

(*2*) The total pounds of lobster landed during that qualifying year.

(C) *Trap allocation formula.* The Regional Administrator shall allocate traps for use in Area 2 based upon the applicant's highest level of Effective Traps Fished during the qualifying year. Effective Traps Fished shall be the lower value of the maximum number of traps reported fished for that qualifying year compared to the predicted number of traps that is required to catch the reported poundage of lobsters for that year as set forth in the Commission's allocation formula identified in Addendum VII to Amendment 3 of the Commission's Interstate Fishery Management Plan for American Lobster.

(D) *Documentary proof.* To satisfy the Area 2 Qualification and Trap Allocation Criteria set forth in paragraphs (a)(7)(viii)(A) and (B) of this section, the applicants will be limited to the following documentary proof:

(*1*) As proof of a valid Federal lobster permit, the applicant must provide a copy of the vessel's current Federal lobster permit. The potential qualifier may, in lieu of providing a copy, provide NMFS with such data that would allow NMFS to identify the Federal lobster permit in its data base, which would at a minimum include: The applicant's name and address, vessel name, and permit number.

(*2*) As proof of traps fished in Area 2 and lobsters landed from Area 2 in either 2001, 2002, or 2003, the applicant must provide the documentation reported to the state of the traps fished and lobsters landed during any of those years as follows:

(*i*) *State records.* An applicant must provide documentation of his or her state reported traps fished and lobster landings in 2001, 2002, or 2003. The landings must have occurred in a state adjacent to Area 2, which the Regional Administrator shall presume to be limited to Massachusetts, Rhode Island, Connecticut, and/or New York. The Regional Administrator shall presume that the permit holder was truthful and accurate when reporting to his or her state the traps fished and lobster landed in 2001, 2002, and 2003 and that the state records of such are the best evidence of traps fished and lobster landed during those years.

(*ii*) *State decision.* An applicant may provide their state's qualification and allocation decision to satisfy the documentary requirements of this section. The Regional Administrator shall accept a state's qualification and allocation decision as prima facie evidence of the Federal qualification and allocation decision. The Regional Administrator shall presume that the state decision is appropriate, but that presumption is rebuttable and the Regional Administrator may choose to disallow the use of the state decision if the state decision was incorrect or based on factors other than those set forth in this section. This state decision may include, not only the initial state qualification and allocation decision, but may also incorporate state trap transfer decisions that the state allowed since the time of the initial allocation decision.

(*iii*) *States lacking reporting.* An applicant may provide Federal Vessel Trip Reports, dealer records, or captain's logbook as documentation in lieu of state records if the applicant can establish by clear and convincing evidence that the involved state did not require the permit holder to report traps or landings during 2001, 2002, or 2003.

(E) *Application period.* Applicants will have 180 days to submit an application. The time period for submitting an application for access to the EEZ portion of Area 2 begins on the date 30 days after publication of this final rule (application period start date) and ends 210 days after the publication of the final rule. Failure to apply for Area 2 by that date shall be considered a waiver of any future claim for trap fishery access into Area 2.

(F) *Appeal of denial of permit.* Any applicant having first applied for initial qualification into the Area 2 trap fishery pursuant to this section, but having been denied access, may appeal to the Regional Administrator within 45 days of the date indicated on the notice of denial. Any such appeal must be in writing. Appeals may be submitted in the following three situations:

(*1*) *Clerical error.* The grounds for administrative appeal shall be that the Regional Administrator erred clerically in concluding that the vessel did not meet the criteria in paragraph (a)(7)(viii) of this section. Errors arising from oversight or omission such as ministerial, mathematical, or typographical mistakes would form the basis of such an appeal. Alleged errors in substance or judgment do not form a sufficient basis of appeal under this paragraph. The appeal must set forth the basis for the applicant's belief that the Regional Administrator's decision was made in error. If the appealing applicant does not clearly and convincingly prove that an error occurred, the appeal must be denied.

(*2*) *Medical or military hardship appeal.* The grounds for a hardship appeal shall be limited to those situations in which medical incapacity or military service prevented a Federal lobster permit holder from fishing for lobster in 2001, 2002, and 2003. If the Federal lobster permit holder is able to prove such a hardship, then the individual shall be granted the additional years of 1999 and 2000 from which to provide documentary proof in order to qualify and fish for traps in Area 2. In order to pursue a Hardship Appeal, the applicant must establish the following by a preponderance of the evidence:

(*i*) *Proof of medical incapacity or military service.* To prove incapacity, the applicant must provide medical documentation from a medical provider, or military service documentation from the military, that establishes that the applicant was incapable of lobster fishing in 2001, 2002, and 2003. An applicant may provide their state's qualification and allocation appeals decision to satisfy the documentary requirements of this section. The Regional Administrator shall accept a state's appeals decision as prima facie evidence of the appeals Federal decision. The Regional Administrator shall presume that the state decision is appropriate, but that presumption is rebuttable and the Regional Administrator may choose to disallow the use of the state decision if the state decision was incorrect or based on factors other than those set forth in this section.

(*ii*) *Proof of Area 2 trap fishing in 1999 and 2000.* To prove a history of Area 2 lobster trap fishing in 1999 and/or 2000, the applicant must provide documentary proof as outlined in paragraph (a)(7)(viii)(D) of this section.

(*3*) *Director's appeal.* A state's marine fisheries agency may appeal on behalf of one of its state permit holders. The only grounds for a Director's Appeal shall be that the Regional Administrator's decision on a dual permit holder's Federal permit has created a detrimental incongruence with the state's earlier decision on that permit holder's state permit. In order to pursue a Director's Appeal, the state must establish the following by a preponderance of the evidence:

(*i*) *Proof of an incongruence.* The state must establish that the individual has a state lobster permit, which the state has

qualified for access with traps into Area 2, as well as a Federal lobster permit, which the Regional Administrator has denied access or restricted the permit's trap allocation into Area 2. The state must establish that the incongruent permits were linked during the year or years used in the initial application such that the fishing history used in Federal and state permit decisions was the same.

(*ii*) *Proof of detriment.* The state must provide a letter supporting the granting of trap access for the Federal permit holder. In the support letter, the state must explain how the incongruence in this instance is detrimental to the Area 2 lobster fishery and why granting the appeal is, on balance, in the best interests of the fishery overall. A showing of detriment to the individual permit holder is not grounds for this appeal and will not be considered relevant to the decision.

(G) *Appellate timing and review.* All appeals must be submitted to the Regional Administrator in writing and reviewed as follows:

(*1*) *Clerical appeals timing.* Applicants must submit Clerical Appeals no later than 45 days after the date on the NMFS Notice of Denial of the Initial Qualification Application. NMFS shall consider the appeal's postmark date as constituting the submission date for the purposes of determining timing. Failure to register an appeal within 45 days of the date of the Notice of Denial will preclude any further appeal. The appellant may notify the Regional Administrator in writing of his or her intent to appeal within the 45 days and request a time extension to procure the necessary documentation. Time extensions shall be limited to 30 days and shall be calculated as extending 30 days beyond the initial 45-day period that begins on the original date on the Notice of Denial. Appeals submitted beyond the deadlines stated herein will not be accepted.

(*2*) *Medical or military appeals timing.* Applicants must submit Medical or Military Appeals no later than 45 days after the date on the NMFS Notice of Denial of the Initial Qualification Application. NMFS shall consider the appeal's postmark date as constituting the submission date for the purposes of determining timing. Failure to register an appeal within 45 days of the date of the Notice of Denial will preclude any further appeal. The appellant may notify the Regional Administrator in writing of his or her intent to appeal within the 45 days and request a time extension to procure the necessary documentation. Time extensions shall be limited to 30 days and shall be calculated as extending 30 days beyond the initial 45-day period that begins on the original date on the Notice of Denial. Appeals submitted beyond the deadlines stated herein will not be accepted.

(*3*) *Director's appeals timing.* State Directors must submit Director's Appeals on behalf of their constituents no later than 180 days after the date of the NMFS Notice of Denial of the Initial Qualification Application. NMFS shall consider the appeal's postmark date as constituting the submission date for the purposes of determining timing. Failure to register an appeal within 180 days of the date of the Notice of Denial will preclude any further appeal. The Director may notify the Regional Administrator in writing of his or her intent to appeal within the 180 days and request a time extension to procure the necessary documentation. Time extensions shall be limited to 30 days and shall be calculated as extending 30 days beyond the initial 180-day period that begins on the original date on the Notice of Denial. Appeals submitted beyond the deadline will not be accepted.

(*4*) *Agency response.* Upon receipt of a complete written appeal with supporting documentation in the time frame allowable, the Regional Administrator will then appoint an appeals officer who will review the appellate documentation. After completing a review of the appeal, the appeals officer will make findings and a recommendation, which shall be advisory only, to the Regional Administrator, who shall make the final agency decision whether to qualify the applicant.

(H) *Status of vessels pending appeal.* The Regional Administrator may authorize a vessel to fish with traps in Area 2 during an appeal. The Regional Administrator may do so by issuing a letter authorizing the appellant to fish up to 800 traps in Area 2 during the pendency of the appeal. The Regional Administrator's letter must be present onboard the vessel while it is engaged in such fishing in order for the vessel to be authorized. If the appeal is ultimately denied, the Regional Administrator's letter authorizing fishing during the appeal will become invalid 5 days after receipt of the notice of appellate denial or 15 days after the date on the notice of appellate denial, whichever occurs first.

* * * * *

■ 3. In § 697.7, add paragraph (c)(1)(xxx) to read as follows:

§ 697.7 Prohibitions.

* * * * *

(c) * * *

(1) * * *

(xxx) The Federal waters of the Outer Cape Area shall be closed to lobster fishing with traps by Federal lobster permit holders from January 15th through March 15th.

(A) Lobster fishing with traps is prohibited in the Outer Cape Area during this seasonal closure. Federal trap fishers are prohibited from possessing or landing lobster taken from the Outer Cape Area during the seasonal closure.

(B) All lobster traps must be removed from Outer Cape Area waters before the start of the seasonal closure and may not be re-deployed into Area waters until after the seasonal closure ends. Federal trap fishers are prohibited from setting, hauling, storing, abandoning or in any way leaving their traps in Outer Cape Area waters during this seasonal closure. Federal lobster permit holders are prohibited from possessing or carrying lobster traps aboard a vessel in Outer Cape Area waters during this seasonal closure unless the vessel is transiting through the Outer Cape Area pursuant to paragraph (c)(1)(xxx)(D) of this section.

(C) The Outer Cape Area seasonal closure relates only to the Outer Cape Area. The restrictive provisions of § 697.3 and § 697.4(a)(7)(v) do not apply to this closure. Federal lobster permit holders with an Outer Cape Area designation and another Lobster Management Area designation on their Federal lobster permit would not have to similarly remove their lobster gear from the other designated management areas.

(D) Transiting Outer Cape Area. Federal lobster permit holders may possess lobster traps on their vessel in the Outer Cape Area during the seasonal closure only if:

(*1*) The trap gear is stowed; and

(*2*) The vessel is transiting the Outer Cape Area. For the purposes of this section transiting shall mean passing through the Outer Cape Area without stopping to reach a destination outside the Outer Cape Area.

(E) The Regional Administrator may authorize a permit holder or vessel owner to haul ashore lobster traps from the Outer Cape Area during the seasonal closure without having to engage in the exempted fishing process in § 697.22, if the permit holder or vessel owner can establish the following:

(*1*) That the lobster traps were not able to be hauled ashore before the seasonal closure due to incapacity, vessel/mechanical inoperability, and/or poor weather; and

(*2*) That all lobsters caught in the subject traps will be immediately returned to the sea.

(*3*) The Regional Administrator may condition this authorization as appropriate in order to maintain the overall integrity of the closure.

* * * * *

■ 4. Revise § 697.19 to read as follows:

§ 697.19 Trap limits and trap tag requirements for vessels fishing with lobster traps.

(a) *Area 1 trap limits.* The Area 1 trap limit is capped at 800 traps. Federally permitted lobster fishing vessels shall not fish with, deploy in, possess in, or haul back more than 800 lobster traps in Area 1.

(b) *Area 2 trap limits.* The Area 2 trap limit is capped at 800 traps. Federally permitted lobster fishing vessels shall not fish with, deploy in, possess in, or haul back more than 800 lobster traps in Area 2.

(c) *Area 3 trap limits.* The Area 3 trap limit is capped at 1,945 traps. Federally permitted lobster fishing vessels shall not fish with, deploy in, possess in, or haul back more than 1,945 lobster traps in Area 3.

(d) *Area 4 trap limits.* The Area 4 trap limit is capped at 1,440 traps. Federally permitted lobster fishing vessels shall not fish with, deploy in, possess in, or haul back more than 1,440 lobster traps in Area 4.

(e) *Area 5 trap limits.* The Area 5 trap limit is capped at 1,440 traps, unless the vessel is operating under an Area 5 Trap Waiver permit issued under § 697.26. Federally permitted lobster fishing vessels shall not fish with, deploy in, possess in, or haul back more than 1,440 lobster traps in Area 5, unless the vessel is operating under an Area 5 Trap Waiver permit issued under § 697.26.

(f) *Outer Cape Area.* The Outer Cape Area trap limit is capped at 800 traps. Federally permitted lobster fishing vessels shall not fish with, deploy in, possess in, or haul back more than 800 lobster traps in the Outer Cape Area.

(g) *Lobster trap limits for vessels fishing or authorized to fish in more than one EEZ management area.* A vessel owner who elects to fish in more than one EEZ Management Area is restricted to the lowest cap limit of the areas and may not fish with, deploy in, possess in, or haul back from any of those elected management areas more lobster traps than the lowest number of lobster traps allocated to that vessel for any one elected management area.

(h) *Conservation equivalent trap limits in New Hampshire state waters.* Notwithstanding any other provision, any vessel with a Federal lobster permit and a New Hampshire Full Commercial Lobster license may fish up to a maximum of 1,200 lobster traps in New Hampshire state waters, to the extent authorized by New Hampshire lobster fishery regulations. However, such vessel may not fish, possess, deploy, or haul back more than 800 lobster traps in the Federal waters of EEZ Nearshore Management Area 1, and may not fish more than a combined total of 1,200 lobster traps in the Federal and New Hampshire state waters portions of EEZ Nearshore Management Area 1.

(i) *Trap tag requirements for vessels fishing with lobster traps.* Any lobster trap fished in Federal waters must have a valid Federal lobster trap tag permanently attached to the trap bridge or central cross-member. Any vessel with a Federal lobster permit may not possess, deploy, or haul back lobster traps in any portion of any management area that do not have a valid, federally recognized lobster trap tag permanently attached to the trap bridge or central cross-member.

(j) *Maximum lobster trap tags authorized for direct purchase.* In any fishing year, the maximum number of tags authorized for direct purchase by each permit holder is the applicable trap limit specified in paragraphs (a) through (f) of this section plus an additional 10 percent to cover trap loss.

(k) *EEZ Management Area 5 trap waiver exemption.* Any vessel issued an Area 5 Trap Waiver permit under § 697.4(p) is exempt from the provisions of this section.

■ 5. Add § 697.27 to read as follows:

§ 697.27 Trap transferability.

(a) Federal lobster permit holders may elect to participate in a program that allows them to transfer trap allocation to other participating Federal lobster permit holders, subject to the following conditions:

(1) *Participation requirements.* In order to be eligible to participate in the Federal Trap Transfer Program:

(i) An individual must possess a valid Federal lobster permit; and

(ii) If the individual is dually permitted with both Federal and state lobster licenses, the individual must agree to synchronize their state and Federal allocations in each area for which there is an allocation. This synchronization shall be set at the lower of the state or federal allocation in each area. This provision does not apply to Areas 1 and 6 as neither area have a Federal trap allocation.

(iii) Individuals participating in the Lobster Management Area 1 trap fishery may participate in the Trap Transfer Program, but doing so may result in forfeiture of future participation in the Area 1 trap fishery as follows:

(A) Area 1 fishers may accept, receive, or purchase trap allocations up to their Area 1 trap limit identified in § 697.19 and fish with that allocation both in Area 1 and the other area or areas subject to the restrictive provisions of § 697.3 and § 697.4(a)(7)(v).

(B) Area 1 fishers with trap allocations in Areas 2, 3 and/or the Outer Cape Area may transfer away or sell any portion of that allocation, but in so doing, the Area 1 fisher shall forfeit any right to fish in Area 1 with traps in the future.

(2) *Trap allocation transfers.* Trap allocation transfers will be allowed subject to the following conditions:

(i) *State/federal alignment.* Participants with dual state and Federal permits may participate in the Trap Transfer Program each year, but their state and Federal trap allocations must be aligned as required in paragraph (a)(1)(ii) of this section at the start and close of each trap transfer period.

(ii) *Eligible traps.* Buyers and sellers may only transfer trap allocations from Lobster Management Areas 2, 3, and the Outer Cape Area.

(iii) *Debiting remaining allocation.* The permit holder transferring trap allocations shall have his or her remaining Federal trap allocation in all Lobster Conservation Management Areas debited by the total amount of allocation transferred. This provision does not apply to Areas 1 and 6, as neither area have a Federal trap allocation. A seller may not transfer a trap allocation if, after the transfer is debited, the allocation in any remaining Lobster Conservation Management Area would be below zero.

(iv) *Crediting allocations for partial trap transfers.* In a partial trap transfer, where the transfer is occurring independent of a Federal lobster permit transfer, the permit holder receiving the transferred allocation shall have his or her allocation credited as follows:

(A) *Trap retirement.* All permit holders receiving trap allocation transfers shall retire 10 percent of that transferred allocation from the fishery for conservation. This provision does not pertain to full business transfers where the transfer includes the transfer of a Federal lobster permit and all traps associated with that permit.

(B) *Multi-Area trap allocation history.* To the extent that transferred trap allocations have been granted access into multiple management areas, the recipient must choose a single management area in which that transferred allocation will be fished. Upon choosing the single management

area, whatever multi-area fishing history previously associated with that transferred allocation shall be considered lost and shall not serve as a basis for future multi-area access. The trap allocation retirement percentages shall be calculated according to the area chosen.

(C) *Single management area trap allocation history.* A trap may only be fished in an area for which it was allocated.

(D) All trap allocation transfers are subject to whatever trap allocation cap exists in the involved lobster management area. No participant may receive a transfer that, when combined with existing allocation, would put that permit holder's trap allocation above the involved trap caps identified in § 697.19.

(v) Trap allocations may only be transferred in ten trap increments.

(vi) Trap allocation transfers must be approved by the Regional Administrator before becoming effective. The Regional Administrator shall approve a transfer upon a showing by the involved permit holders of the following:

(A) The proposed transfer is documented in a legible written agreement signed and dated by the involved permit holders. The agreement must identify the amount of allocation being transferred as well as the Federal lobster permit number from which the allocation is being taken and the Federal lobster permit number that is receiving the allocation. If the transfer involves parties who also possess a state lobster license, the parties must identify the state lobster license number and state of issuance.

(B) That the transferring permit holder has sufficient allocation to transfer and that the permit holder's post-transfer allocation is clear and agreed to.

(C) That the permit holder receiving the transfer has sufficient room under any applicable trap cap identified in § 697.19 to receive the transferred allocation and that the recipient's post-transfer allocation is clear and agreed to.

(3) *Trap transfer period.* The timing of the Trap Transfer Program is as follows:

(i) Federal lobster permit holders must declare their election into the program in writing to the NMFS Permit Office. Electing into the Trap Transfer Program is a one-time declaration, and the permit holder may participate in the program in later years without needing to re-elect into the program year after year. Federal permit holders may elect into the program at any time in any year, but their ability to actively transfer traps will be limited by the timing restrictions identified in paragraphs (a)(3)(ii) and (iii) of this section.

(ii) All trap transfer requests must be made in writing before September 30 each year, and if approved, will become effective at the start of the next fishing year. The Regional Administrator shall attempt to review, reconcile and notify the transferring parties of the disposition of the requested transfer before December 31 each year. Transfers are not valid until approved by the Regional Administrator.

(iii) *Year 1.* The timing of the first year of the Transfer Program is impacted by the timing of the final rule implementing the program. As a result, in Year 1 of the program only, and notwithstanding paragraph (a)(3)(ii) of this section, NMFS will allow participation in the Program as follows:

(A) Federal permit holders may elect into the Trap Transfer Program beginning 120 days after the publication of the final rule establishing the program;

(B) Federal permit holders may request trap transfers beginning 120 days after the publication of the final rule and ending 150 days after the publication of the final rule, and if approved will be effective at the start of the new fishing year. Transfer requests postmarked later than 150 days after the final rule will not be accepted. The Regional Administrator shall attempt to review, reconcile and notify the transferring parties of the disposition of the requested transfer within two months (within 210 days of the publication of the final rule). Transfers are not valid until approved by the Regional Administrator.

(b) [Reserved]

[FR Doc. 2013–13709 Filed 6–11–13; 8:45 am]

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Notices

Federal Register

Vol. 78, No. 113

Wednesday, June 12, 2013

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Rural Business—Cooperative Service

Inviting Applications for Small Socially-Disadvantaged Producer Grants

AGENCY: Rural Business—Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Business—Cooperative Service announces the availability of $2,855,222 in competitive grant funds for the FY 2013 Small Socially-Disadvantaged Producer Grants (SSDPG) program as authorized by H.R. 933. We are requesting proposals from applicants that will provide technical assistance to small, socially-disadvantaged agricultural producers in rural areas. Eligible applicants include Cooperatives, Groups of Cooperatives, and Cooperative Development Centers. The maximum award per grant is $200,000. The grant period is limited to a one-year timeframe.

DATES: Completed applications for grants must be submitted on paper or electronically according to the following deadlines:

Paper copies must be postmarked and mailed, shipped, or sent overnight no later than July 15, 2013, to be eligible for FY 2013 grant funding. You may also hand carry your application to one of our field offices, but it must be received by close of business on the July 15, 2013, deadline date. Late applications will not be eligible for FY 2013 grant funding.

Electronic copies must be received by *http://www.grants.gov* no later than midnight eastern time July 10, 2013, to be eligible for FY 2013 grant funding. Please review the Grants.gov Web site at *http://grants.gov/applicants/organization_registration.jsp* for instructions on the process of registering your organization as soon as possible to ensure you are able to meet the electronic application deadline.

If you do not meet the deadline for submitting an electronic application, you may hand carry or submit a paper application by the July 15, 2013, deadline as discussed above. Late applications will not be eligible for FY 2013 grant funding.

ADDRESSES: You should contact the USDA Rural Development State Office (State Office) located in the State where you are headquartered if you have questions. You are encouraged to contact your State Office well in advance of the application deadline to discuss your project and ask any questions about the application process. Program guidance as well as application templates may be obtained at *http://www.rurdev.usda.gov/BCP_SSDPG.html.* If you want to submit an electronic application, follow the instructions for the SSDPG funding announcement located at *http://www.grants.gov.* If you want to submit a paper application, send it to the State Office located in the State where you are headquartered. If you are headquartered in Washington, DC, please contact the Office of the Deputy Administrator, Cooperative Programs, Rural Business—Cooperative Service, at (202) 720–7558 for guidance on where to submit your application.

Application materials for the SSDPG program may be obtained at *http://www.rurdev.usda.gov/BCP_SSDPG.html* or by contacting your USDA Rural Development State Office. Contact information for State Offices can be found at *http://www.rurdev.usda.gov/recd_map.html.*

FOR FURTHER INFORMATION CONTACT: Office of the Deputy Administrator, Cooperative Programs, Rural Business—Cooperative Service, United States Department of Agriculture, 1400 Independence Avenue SW., Mail Stop-3250, Room 4016-South, Washington, DC 20250–3250, (202) 720–7558.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency Name: USDA Rural Business Cooperative Service.

Funding Opportunity Title: Small, Socially-Disadvantaged Producer Grant.

Announcement Type: Initial funding request.

Catalog of Federal Domestic Assistance Number: 10.771.

Dates: Application Deadline. You must submit your complete application by July 15, 2013, or it will not be considered for FY 2013 grant funding. Electronic applications must be received by *http://www.grants.gov* no later than midnight Eastern Time July 10, 2013, or it will not be considered for FY 2013 grant funding.

I. Funding Opportunity Description

The SSDPG Program is authorized by 310B(e) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1932). The primary objective of the SSDPG program is to provide Technical Assistance to Small, Socially-Disadvantaged Agricultural Producers. Grants are awarded on a competitive basis. The maximum award amount per grant is $200,000. Grants are available for Cooperative Development Centers, individual Cooperatives, or Groups of Cooperatives that serve socially-disadvantaged groups and where a majority of the boards or directors or governing board is comprised of members of socially-disadvantaged groups.

Definitions

Agency—Rural Business—Cooperative Service, an agency of the United States Department of Agriculture (USDA) Rural Development or a successor agency.

Agricultural Commodity—An unprocessed product of farms, ranches, nurseries, and forests. Agricultural commodities include: livestock, poultry, and fish; fruits and vegetables; grains, such as wheat, barley, oats, rye, triticale, rice, corn, and sorghum; legumes, such as field beans and peas; animal feed and forage crops; seed crops; fiber crops, such as cotton; oil crops, such as safflower, sunflower, corn, and cottonseed; trees grown for lumber and wood products; nursery stock grown commercially; Christmas trees; ornamentals and cut flowers; and turf grown commercially for sod. Agricultural commodities do not include horses or animals raised as pets, such as cats, dogs, and ferrets.

Conflict of Interest—A situation in which the ability of a person or entity to act impartially would be questionable due to competing professional or personal interests. An example of conflict of interest occurs when the grantee's employees, board of directors, including their immediate family, have

a legal or personal financial interest in the recipients receiving the benefits or services of the grant. Another example of conflict of interest includes paying Small Socially-Disadvantaged Producers to provide Technical Assistance to other Small Socially-Disadvantaged Producers.

Cooperative—A farmer- or rancher-owned and -controlled business, organized and chartered as a cooperative, from which benefits are derived and distributed equitably on the basis of use by each of the farmer or rancher owners whose primary focus is to provide assistance to Small, Socially-Disadvantaged Agricultural Producers and where a majority of the board of directors or governing board is comprised of individuals who are members of socially-disadvantaged groups.

Cooperative Development Center—A nonprofit corporation or accredited institution of higher education that is currently being operated by the grantee for rural cooperative development and where a majority of the board of directors or governing board is comprised of individuals who are members of socially-disadvantaged groups. It may or may not be an independent legal entity separate from the grantee. The Center's main objective is to assist Cooperatives with their startup, expansion or operational improvement in order to promote development in rural areas of services and products, processes that can be used in the marketing of products, or enterprises that create Value-Added to farm products through processing or marketing activities. Cooperative development activities may include, but are not limited to, Technical Assistance, research services, educational services and advisory services. Operational improvement includes making the Cooperative more efficient or better managed.

Cooperative Services—The office within Rural Business-Cooperative Service, and any successor organization, that administers programs authorized by the Cooperative Marketing Act of 1926 (7 U.S.C. 451 *et seq.*) and such other programs identified in USDA regulations.

Economic Development—The economic growth of an area as evidenced by increase in total income, employment opportunities, decreased out-migration of population, value of production, increased diversification of industry, higher labor force participation rates, increased duration of employment, higher wage levels, or gains in other measurements of economic activity, such as land values.

Feasibility Study—An analysis of the economic, market, technical, financial, and management feasibility of a proposed Project.

Group of Cooperatives—A group of Cooperatives whose primary focus is to provide assistance to Small, Socially-Disadvantaged Agricultural Producers and where a majority of the board of directors or governing board is comprised of individuals who are members of socially-disadvantaged groups.

Operating Cost—The day-to-day expenses of running a business; for example: utilities, rent, salaries, depreciation, product production costs, marketing and advertising, and other basic overhead items.

Project—Includes all activities to be funded by the Small Socially-Disadvantaged Producer Grant.

Rural and Rural Area—Any area of a State:

(1) Not in a city or town that has a population of more than 50,000 inhabitants, according to the latest decennial census of the United States; and

(2) The contiguous and adjacent urbanized area,

(3) Urbanized areas that are rural in character as defined by 7 U.S.C. 1991(a)(13), as amended by Section 6018 of the Food, Conservation, and Energy Act of 2008, Public Law 110–246 (June 18, 2008).

(4) For the purposes of this definition, cities and towns are incorporated population centers with definite boundaries, local self-government, and legal powers set forth in a charter granted by the State. Notwithstanding any other provision of this paragraph, within the areas of the County of Honolulu, Hawaii, and the Commonwealth of Puerto Rico, the Secretary may designate any part of the areas as a rural area if the Secretary determines that the part is not urban in character, other than any area included in the Honolulu census designated place (CDP) or the San Juan CDP.

Rural Development—A mission area within USDA consisting of the Office of Under Secretary for Rural Development, Rural Business-Cooperative Services, Rural Housing Service, and Rural Utilities Service and any successors.

Small, Socially-Disadvantaged Producer—Socially-Disadvantaged persons including farmers, ranchers, loggers, agricultural harvesters, and fishermen, that have averaged $250,000 or less in annual gross sales of agricultural products in the last 3 years.

Socially-Disadvantaged Producer—Individual agricultural producer who is a member of a group whose members have been subjected to racial, ethnic or gender prejudice, without regard for their individual qualities.

State—Includes each of the 50 states, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and, as may be determined by the Secretary to be feasible, appropriate and lawful, the Federated States of Micronesia, the Republic of the Marshall Islands and the Republic of Palau.

Technical Assistance—An advisory service performed for the benefit of a Small, Socially-Disadvantaged Producer such as market research; product and/or service improvement; legal advice and assistance; Feasibility Study, business plan, and marketing plan development; and training. Technical Assistance does not include the Operating Costs of a cooperative being assisted.

Value-Added—The incremental value that is realized by the producer from an agricultural commodity or product as the result of a change in its physical state, differentiated production or marketing, as demonstrated in a business plan, or product segregation. Incremental value may be realized by the producer as a result of either an increase in value to buyers or the expansion of the overall market for the product. Examples include milling wheat into flour, slaughtering livestock or poultry, making strawberries into jam, and marketing of organic products.

II. Award Information

Type of Award: Grant.
Fiscal Year Funds: FY 2013.
Total Funding: $2,855,222.
Maximum Award: $200,000.
Project Period: 1 year.
Anticipated Award Date: September 1, 2013.

III. Eligibility Information

A. *Eligible Applicants.* Grants may be made to Cooperatives, Groups of Cooperatives, and Cooperative Development Centers where a majority of the board of directors or governing board is comprised of individuals who are members of socially-disadvantaged groups. You must be able to verify your legal structure in the State in which you are incorporated. Grants may not be made to public bodies or to individuals.

An applicant must obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) number and register in the System for Awards Management (SAM, formally managed by the Central Contractor Registry (CCR)) prior to submitting an application. (See 2 CFR 25.200(b)). An applicant must provide

their DUNS number in the application. In addition, an applicant must maintain its registration in SAM during the time its application is active. Finally, an applicant must have the necessary processes and systems in place to comply with the reporting requirements in 2 CFR 170.200(b), as long as it is not exempted from reporting. Exemptions are identified at 2 CFR 170.110(b).

B. *Cost Sharing or Matching.* No matching funds are required.

C. *Other Eligibility Requirements*

Use of Funds: Funds may only be used for Technical Assistance Projects as defined in this Notice.

Project Area Eligibility: The proposed Project must take place in a Rural Area as defined in this Notice.

Grant Period Eligibility: If awarded, grant funds must be used within 12 months. Applications must have a time frame of one year or less. Your proposed time frame should begin no earlier than the grant award date and end no later than December 31, 2014. However, you should note that the anticipated award date is September 1, so your proposed start date should be after September 1, 2013. Projects must be completed within the 12-month time frame. The Agency may approve requests to extend the grant period for up to an additional 12 months at its discretion. Further guidance on grant period extensions will be provided in the award document. Applications that request funds for a time period ending after December 31, 2014, will not be considered for funding.

If you have an existing SSDPG award, you must be performing satisfactorily to be considered eligible for a new award. Satisfactory performance includes being up-to-date on all financial and performance reports and being current on all tasks as approved in the work plan. The Agency will use its discretion to make this determination.

Completeness Eligibility: Your application must provide all of the information requested in Section IV(C) of this Notice. Applications lacking sufficient information to determine eligibility and scoring will be considered ineligible.

Multiple Grant Eligibility: You may only submit one SSDPG grant application each funding cycle.

Activity Eligibility: Your application must propose Technical Assistance that will benefit Small Socially-Disadvantaged Producers in Rural Areas. Please review section IV(H) of this Notice, ''Funding Restrictions,'' carefully.

IV. Application and Submission Information

A. Address To Request Application Package

The application package for applying on paper for this funding opportunity is located at *http://www.rurdev.usda.gov/BCP_SSDPG.html.* You may also contact your USDA Rural Development State Office for more information. Contact information for State Offices is located at *http://www.rurdev.usda.gov/recd_map.html.*

B. Form of Submission

- You may submit your application in paper form or electronically. If you submit in paper form, any forms requiring signatures must include an original signature. To submit an application electronically, you must use the Grants.gov Web site at *http://www.grants.gov.* You may not submit an application electronically in any way other than through Grants.gov.
- When you enter the Grants.gov Web site, you will find information about submitting an application electronically through the site, as well as the hours of operation.
- To use Grants.gov, you must have a DUNS number, which can be obtained at no cost via a toll-free request line at (866) 705–5711. Please note that obtaining the DUNS number is required prior to submitting an application. You must also maintain registration in SAM (formerly the CCR database). (See 2 CFR part 25.) You may register for SAM at *https://www.sam.gov/portal/public/SAM/.* You must submit all of your application documents electronically through Grants.gov.
- After electronically submitting an application through Grants.gov, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number.
- You may be required to provide original signatures on forms at a later date.
- You can locate the Grants.gov downloadable application package for this program by using a keyword, the program name, the Catalog of Federal Domestic Assistance Number, or the Funding Opportunity Number.

C. Application Content

Your application must contain the following required forms and proposal elements:

1. Form SF–424, ''Application for Federal Assistance,'' must be completed, signed, and include a DUNS number. Since there are no specific fields for a Commercial and Government Entity (CAGE) code and expiration date, you may identify them anywhere you want to on the SF 424. If you do not include the CAGE code and expiration date and the DUNS number in your application, it will not be considered for funding.

2. Form SF–424A, ''Budget Information-Non-Construction Programs.'' This form must be completed and submitted as part of the application package.

3. Form SF–424B, ''Assurances—Non-Construction Programs.'' This form must be completed, signed, and submitted as part of the application package.

4. You must complete Form AD–3030, ''Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants,'' if you are a corporation. A corporation is any entity that has filed articles of incorporation in one of the 50 States, the District of Columbia, or the various territories of the United States including American Samoa, Federated States of Micronesia, Guam, Midway Islands, Northern Mariana Islands, Puerto Rico, Republic of Palau, Republic of the Marshall Islands, or the U.S. Virgin Islands. Corporations include both for profit and non-profit entities.

5. Table of Contents. Your application must contain a detailed Table of Contents (TOC) immediately following the SF–424B. The TOC must include page numbers for each part of the application. Page numbers should begin immediately following the TOC.

6. Executive Summary. A summary of the proposal, not to exceed one page, must briefly describe the Project, tasks to be completed, and other relevant information that provides a general overview of the Project.

7. Eligibility Discussion. A detailed discussion, not to exceed four pages, must describe how you meet the following requirements:

(i) Applicant Eligibility. You must describe how you meet the definition of a Cooperative, Group of Cooperatives, or Cooperative Development Center. Your application must show that a majority of the board of directors or governing board is comprised of individuals who are members of socially-disadvantaged groups. If applying as a Cooperative or a Group of Cooperatives, you must verify your incorporation and status in the State that you have applied by providing the State's Certificate of Good Standing, your Articles of Incorporation, and By-Laws. If you are a nonprofit corporation applying as a Cooperative Development Center, you must provide evidence of your status as a nonprofit corporation in good standing, your Articles of Incorporation and a copy of your mission statement. If you are an

institution of higher education applying as a Cooperative Development Center, you must provide evidence of your status as an accredited institution of higher education and a copy of your mission statement. You must apply as only one type of applicant. If the requested verification documents are not included, your application will not be considered for funding.

(ii) Use of Funds. You must provide a detailed discussion on how the proposed Project activities meet the definition of Technical Assistance and identify the group(s) of socially-disadvantaged producers that will be assisted.

(iii) Project Area. You must provide specific information that details the location of the Project area and explain how the area meets the definition of ''Rural Area.''

(iv) Grant Period. You must provide a time frame for the proposed Project and discuss how the Project will be completed within that time frame.

8. Budget/Work plan. You must describe, in detail not to exceed four pages, the purpose of the grant, what type of assistance will be provided, and the total amount of funds needed for the Project. The budget must also present a breakdown of estimated costs associated with each task/activity for each Project. The amount of grant funds requested will be reduced if the applicant does not have justification for all costs. You must discuss at a minimum:

a. Specific tasks to be completed using grant funds;

b. How socially-disadvantaged producers will be identified;

c. Key personnel;

d. The evaluation methods to be used to determine the success of specific tasks and overall Project objectives.

The budget must present a breakdown of the estimated costs associated with Project activities and allocate these costs to each of the tasks to be undertaken.

9. Evaluation Criteria. Each of the evaluation criteria in this Notice must be addressed in narrative form, with a maximum of two pages for each individual evaluation criteria. Failure to address each evaluation criteria will result in the application being determined ineligible.

D. Submission Dates and Times

Application Deadline Date: July 15, 2013, for paper applications. July 10, 2013, for electronic applications.

Explanation of Deadlines: Paper applications must be *postmarked* and mailed, shipped, or sent overnight by the deadline date. Electronic applications must be *received* by *http://www.grants.gov* by the deadline date. If your application does not meet the deadline, it will not be considered for funding. You will be notified if your application did not meet the submission deadline.

E. National Environmental Policy Act

We have determined that the activities proposed under the SSDPG program do not have a significant effect on the quality of the environment. You do NOT have to submit an Environmental Impact Statement. See 7 CFR part 1940, subpart G.

F. Civil Rights Compliance Requirements

All grants made under this Notice are subject to Title VI of the Civil Rights Act of 1964 as required by the USDA (7 CFR part 15, subpart A) and Section 504 of the Rehabilitation Act of 1973.

G. Intergovernmental Review of Applications

Executive Order (EO) 12372, Intergovernmental Review of Federal Programs, applies to this program. This EO requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many States have established a Single Point of Contact (SPOC) to facilitate this consultation. A list of States that maintain a SPOC may be obtained at *http://www.whitehouse.gov/omb/grants_spoc.* If your State has a SPOC, you may submit your application directly for review. Any comments obtained through the SPOC must be provided to Rural Development for consideration as part of your application. If your State has not established a SPOC or you do not want to submit your application to the SPOC, Rural Development will submit your application to the SPOC or other appropriate agency or agencies.

You are also encouraged to contact Cooperative Programs at 202–720–8460 or *cpgrants@wdc.usda.gov* if you have questions about this process.

H. Funding Restrictions

Grant funds must be used for Technical Assistance. No funds made available under this solicitation shall be used to:

1. Plan, repair, rehabilitate, acquire, or construct a building or facility, including a processing facility;

2. Purchase, rent, or install fixed equipment, including processing equipment;

3. Purchase vehicles, including boats;

4. Pay for the preparation of the grant application;

5. Pay expenses not directly related to the funded Project;

6. Fund political or lobbying activities;

7. Fund any activities prohibited by 7 CFR parts 3015 or 3019;

8. Fund architectural or engineering design work for a specific physical facility;

9. Fund any direct expenses for the production of any commodity or product to which value will be added, including seed, rootstock, labor for harvesting the crop, and delivery of the commodity to a processing facility;

10. Fund research and development;

11. Purchase land;

12. Duplicate current activities or activities paid for by other funded grant programs.

13. Pay costs of the Project incurred prior to the date of grant approval;

14. Pay for assistance to any private business enterprise that does not have at least 51 percent ownership by those who are either citizens of the United States or reside in the United States after being legally admitted for permanent residence;

15. Pay any judgment or debt owed to the United States;

16. Pay the Operating Costs of the Cooperative, Group of Cooperatives, or Cooperative Development Center;

17. Pay expenses for applicant employee training; or

18. Pay for any goods or services from a person who has a Conflict of Interest with the grantee.

In addition, your application will not be considered for funding if it does any of the following:

- Requests more than the maximum grant amount; or
- Proposes ineligible costs that equal more than 10 percent of total project costs.

We will consider your application for funding if it includes ineligible costs of 10 percent or less of total project costs, as long as it is determined eligible otherwise. However, if your application is successful, those ineligible costs must be removed and replaced with eligible costs, before the Agency will make the grant award, or the amount of the grant award will be reduced accordingly. If we cannot determine the percentage of ineligible costs, your application will not be considered for funding.

V. Application Review Information

A. Application and Scoring Process

The State Offices will review applications to determine if they are eligible for assistance based on requirements in this Notice, and other applicable Federal regulations. If determined eligible, your application will be scored by a panel of USDA

employees in accordance with the point allocation specified in this Notice. A recommendation will be submitted to the Administrator to fund applications in highest ranking order. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion.

B. Scoring Criteria

All eligible and complete applications will be evaluated based on the following criteria. Failure to address any one of the following criteria by the application deadline will result in the application being determined ineligible and the application will not be considered for funding. Evaluators will base scores only on the information provided or cross-referenced by page number in each individual evaluation criterion. The total points possible for the criteria are 60.

1. *Technical Assistance (maximum score of 15 points).* A panel of USDA employees will evaluate your application to determine your ability to assess the needs of Small Socially-Disadvantaged Producers, plan and conduct appropriate and effective Technical Assistance, and identify the expected outcomes of that assistance.

Higher points are awarded if you identify specific needs of the Socially-Disadvantaged Producers to be assisted; clearly explain a logical and detailed plan of assistance for addressing those needs; and discuss realistic outcomes of planned assistance.

2. *Experience (maximum score of 15 points).* A panel of USDA employees will evaluate your length of experience of identified staff or consultants in providing Technical Assistance, as defined in this Notice. You must describe the specific type of Technical Assistance experience for each identified staff member or consultant, as well as years of experience in providing that assistance. In addition, resumes for each individual staff member or consultant must be included as an attachment, listing their experience for the type of Technical Assistance proposed. The attachments will not count toward the maximum page total. We will compare the described experience to the work plan to determine relevance of the experience. Applications that do not include the attached resumes will not be considered for funding.

Higher points will be awarded if a majority of identified staff or consultants demonstrate 5 or more years of experience in providing relevant Technical Assistance. Maximum points will be awarded if all of the identified staff or consultants demonstrate 5 or more years of experience in providing relevant Technical Assistance.

3. *Commitment (maximum of 15 points).* A panel of USDA employees will evaluate your commitment to providing Technical Assistance to Small, Socially-Disadvantaged Producers in Rural Areas. You must list the number and location of Small, Socially-Disadvantaged Producers that will directly benefit from the assistance provided. Higher points will be awarded for Projects that benefit at least 50 Small, Socially-Disadvantaged Producers. If you define and describe the underserved and economically distressed areas within your service area, provide statistics, and identify projects within or affecting these areas, as appropriate, you will score higher on this factor.

4. *Work Plan/Budget (maximum of 10 points).* A panel of USDA employees will evaluate your work plan for detailed actions and an accompanying timetable for implementing the proposal. Clear, logical, realistic, and efficient plans will result in a higher score. Budgets will be reviewed for completeness. You must discuss at a minimum:

a. Specific tasks to be completed using grant funds;

b. How customers will be identified;

c. Key personnel; and

d. The evaluation methods to be used to determine the success of specific tasks and overall project objectives.

5. *Local support (maximum of 5 points).* A panel of USDA employees will evaluate your application for local support of the Technical Assistance activities. Applicants that demonstrate strong support from potential beneficiaries and other developmental organizations will receive more points than those not showing such support.

(i) 0 points are awarded if you do not address this criterion.

(ii) 1 point is awarded if you provide 2–3 support letters that show support from potential beneficiaries and/or support from local organizations.

(iii) 2 points are awarded if you provide 4–5 support letters that show support from potential beneficiaries and/or support from local organizations.

(iv) 3 points are awarded if you provide 6–7 support letters that show support from potential beneficiaries and/or support from local organizations.

(v) 4 points are awarded if you provide 8–9 support letters that show support from potential beneficiaries and/or support from local organizations.

(vi) 5 points are awarded if you provide 10 support letters that show support from potential beneficiaries and/or support from local organizations.

You may submit a maximum of 10 letters of support. These letters should be included as an attachment to the application and will not count against the maximum page total. Additional letters from industry groups, commodity groups, local and State government, and similar organizations should be referenced, but not included in the application package. When referencing these letters, provide the name of the organization, date of the letter, the nature of the support, and the name and title of the person signing the letter.

VI. Award Administration Information

A. Award Notices

If your application is successful, you will receive notification regarding funding from the State Office where your application is submitted or headquartered if you submit your application via Grants.gov. You must comply with all applicable statutes, regulations, and notice requirements before the grant award will be approved. If your application is not successful, you will receive notification, including mediation and appeal rights by mail. See 7 CFR part 11 for USDA National Appeals Division procedures.

B. Administrative and National Policy Requirements

Additional requirements that apply to grantees selected for this program can be found in 7 CFR part 4284, subpart A, parts 3015, 3019, 3052 and 2 CFR parts 215 and 417. All recipients of Federal financial assistance are required to report information about first-tier subawards and executive compensation (See 2 CFR part 170). You will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act reporting requirements (See 2 CFR 170.200(b), unless you are exempt under 2 CFR 170.110(b)). These regulations may be obtained at *http://www.gpoaccess.gov/cfr/index.html*.

The following additional requirements apply to grantees selected for this program:

- Agency approved Grant Agreement.
- Letter of Conditions.
- Form RD 1940–1, ''Request for Obligation of Funds.''
- Form RD 1942–46, ''Letter of Intent to Meet Conditions.''
- Form AD–1047, ''Certification Regarding Debarment, Suspension, and Other Responsibility Matters-Primary Covered Transactions.''
- Form AD–1048, ''Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions.''

• Form AD–1049, ''Certification Regarding a Drug-Free Workplace Requirement (Grants).''

• Form AD–3031, ''Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants.''

• Form RD 400–4, ''Assurance Agreement.''

Additional information on these requirements can be found at *http://www.rurdev.usda.gov/BCP_SSDPG.html.*

VII. Agency Contacts

For general questions about this announcement and for program Technical Assistance, please contact the appropriate State Office as indicated in the **ADDRESSES** section of this Notice.

VIII. Non-Discrimination Statement

USDA prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identify, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.)

To File a Program Complaint

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at *http://www.ascr.usda.gov/complain_filing_cust.html,* or at any USDA office, or call (866) 632–9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, by fax (202) 690–7442 or email at *program.intake@usda.gov.*

Persons With Disabilities

Individuals who are deaf, hard of hearing or have speech disabilities and who wish to file either an EEO or program complaint, please contact USDA through the Federal Relay Service at (800) 877–8339 or (800) 845–6136 (in Spanish).

Persons with disabilities, who wish to file a program complaint, please see information above on how to contact us by mail directly or by email. If you require alternative means of communication for program information (e.g., Braille, large print, audiotape, etc.), please contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Dated: June 5, 2013.

Lillian Salerno,

Acting Administrator, Rural Business-Cooperative Service.

[FR Doc. 2013–13867 Filed 6–11–13; 8:45 am]

BILLING CODE 3410–XY–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–838]

Seamless Refined Copper Pipe and Tube from Mexico: Final Results of Antidumping Duty Administrative Review; 2010–2011

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 10, 2012, the Department of Commerce (the Department) published in the **Federal Register** the *Preliminary Results* of the 2010–2011 administrative review of the antidumping duty order on seamless refined copper tube and pipe from Mexico.[1] This review covers two producers/exporters of the subject merchandise, GD Affiliates S. de R.L. de C.V. and its affiliate Hong Kong GD Trading Co., Ltd. (collectively, Golden Dragon) and Nacional de Cobre, S.A. de C.V. (Nacobre).[2] We gave interested parties an opportunity to comment on the *Preliminary Results* and, based upon our analysis of the comments, we continue to find that subject merchandise has not been sold at less than normal value.

DATES: *Effective Date:* June 12, 2013.

FOR FURTHER INFORMATION CONTACT: Elizabeth Eastwood or Dennis McClure, AD/CVD Operations, Office 2, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3874 or (202) 482–5973, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 10, 2012, the Department published in the **Federal Register** the *Preliminary Results* of the 2010–2011 administrative review of the antidumping duty order on seamless copper pipe and tube from Mexico. We invited parties to comment on the *Preliminary Results.* We received case briefs from Nacobre and the petitioners[3] on January 9, 2013. We received rebuttal briefs from Golden Dragon, Nacobre, and the petitioners on January 18, 2013. On March 28, 2013, the Department exercised its discretion to extend the deadline for the final results of this administrative review until June 10, 2013.[4]

Scope of the Order

The merchandise subject to the order[5] is seamless refined copper pipe and tube. The product is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7407.10.1500, 7419.99.5050, 8415.90.8065, and 8415.90.8085. Although the HTSUS numbers are provided for convenience and customs purposes, the written product description, available in *Amended Final and Order,* remains dispositive.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this administrative review are listed in the Appendix to this notice and addressed in the Issues and Decision Memorandum, which is adopted by this notice. Parties can find a complete discussion of all issues raised in this review and the corresponding recommendations in this public memorandum, which is on file electronically via Import

[1] *See Seamless Refined Copper Pipe and Tube From Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2010–2011,* 77 FR 73422 (December 10, 2012) (*Preliminary Results*) and accompanying Decision Memorandum.

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews and Requests for Revocation in Part,* 76 FR 82268 (December 30, 2011); *see also Seamless Refined Copper Pipe and Tube From Mexico: Notice of Partial Rescission of Antidumping Duty Administrative Review,* 77 FR 10476 (February 22, 2012).

[3] The petitioners are Cerro Flow Products, LLC, Wieland Copper Products, LLC, Mueller Copper Tube Products, Inc. and Mueller Copper Tube Company, Inc.

[4] *See* the March 28, 2013, Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, through James Maeder, Director, Office 2, Office of AD/CVD Operations, from Dennis McClure, Analyst, entitled ''Seamless Refined Copper Pipe and Tube from Mexico: Extension of Deadline for Final Results of Antidumping Duty Administrative Review.''

[5] *See Seamless Refined Copper Pipe and Tube From Mexico and the People's Republic of China: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value From Mexico,* 75 FR 71070 (November 22, 2010) (*Amended Final and Order*).

Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov,* and is available to all parties in the Central Records Unit, Room 7046, of the main Department of Commerce building.

In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Web at *http://ia.ita.doc.gov/frn/.* The paper copy and electronic version of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Results

We revised our preliminary margin calculations for Golden Dragon and Nacobre to use the home market sales data they reported in their post-preliminary submissions to the Department. We made no other changes to the calculation of Golden Dragon's and Nacobre's weighted-average dumping margins in these final results.

Period of Review

The period of review is May 1, 2011, through October 31, 2011, for Golden Dragon and November 22, 2010, through October 31, 2011, for Nacobre.

Final Results of the Review

As a result of our review, we determine that sales of the subject merchandise have not been made at prices below normal value for the period May 1, 2011, and October 31, 2011, for Golden Dragon and November 22, 2010, through October 31, 2011, for Nacobre.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Assessment Rate

Pursuant to section 751(a)(2)(C) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.212(b)(1), the Department has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise and deposits of estimated duties, where applicable, in accordance with the final results of this review. The Department intends to issue appropriate assessment instructions directly to CBP 15 days after publication of the final results of this administrative review.

Pursuant to the *Final Modification for Reviews,*[6] because the respondents' weighted-average dumping margins are zero, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.[7]

The Department clarified its ''automatic assessment'' regulation on May 6, 2003.[8] This clarification will apply to entries of subject merchandise during the POR produced by Golden Dragon and Nacobre for which these companies did not know that the merchandise was destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of these final results for all shipments of seamless refined copper pipe and tube from Mexico entered, or withdrawn from warehouse, for consumption on or after the publication date as provided by section 751(a)(2) of the Act: (1) The cash deposit rates for Golden Dragon and Nacobre will be equal to the weighted-average dumping margins established in the final results of this administrative review (*i.e.,* zero percent); (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a completed prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment for the manufacturer of the merchandise; (4) the cash deposit rate for all other manufacturers or exporters will continue to be 26.03 percent, the all-others rate established in the *Amended Final and Order.* These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Order

In accordance with 19 CFR 351.305(a)(3), this notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO, which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation subject to sanction.

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: June 5, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix—Issues and Decision Memorandum

Comment 1: Targeted Dumping Analysis
Comment 2: Date of Sale for Nacobre's ''Fixed Price'' Sales
Comment 3: Nacobre's Indirect Selling Expenses
Comment 4: Nacobre's General and Administrative Expenses
Comment 5: Adjustment to U.S. Price for Golden Dragon

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BILLING CODE 3510–DS–P

[6] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012) (*Final Modification for Reviews*).

[7] *Id.* at 8102.

[8] For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–924]

Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2010–2011

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 10, 2012, the Department of Commerce (''Department'') published its

Preliminary Results of the third administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip (''PET film'') from the People's Republic of China (''PRC'').[1] We gave interested parties an opportunity to comment on the *Preliminary Results.* After reviewing interested parties' comments and information received, we have made changes for the final results of this review. The final antidumping duty margins for this review are listed below in the ''Final Results of the Review'' section of this notice. The period of review (''POR'') is November 1, 2010, through October 31, 2011.

DATES: *Effective Date:* June 12, 2013.

FOR FURTHER INFORMATION CONTACT: Thomas Martin or Jonathan Hill, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3936 and (202) 482–3518 respectively.

SUPPLEMENTARY INFORMATION:

Background

The Department published the *Preliminary Results* on December 10, 2012. In accordance with 19 CFR 351.309(c)(1)(ii), we invited parties to comment on our *Preliminary Results.*[2] On January 28, 2013, the following interested parties filed timely case briefs: Bemis Company, Inc., and its affiliate Curwood Inc.; Shaoxing Xiangyu Green Packing Co., Ltd. (''Green Packing''); Terphane Inc.; Tianjin Wanhua Co., Ltd. (''Wanhua''),[3] Fuwei Films (Shandong) Co., Ltd. (''Fuwei Films''), and Sichuan Dongfang Insulating Material Co., Ltd. (''Dongfang'')[4] (collectively, ''Wanhua *et al.*''); Mitsubishi Polyester Film, Inc., SKC, Inc., and Toray Plastics (America), Inc. (collectively, ''Petitioners''); DuPont Teijin Films China Limited,[5] DuPont Hongji Films Foshan Co., Ltd., and DuPont Teijin Hongji Films Ningbo Co., Ltd. (''DuPont Group''). On February 4, 2013, the following interested parties filed timely rebuttal briefs: Terphane Inc., Petitioners, Green Packing, DuPont Group, and Wanhua *et al.*[6]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties are addressed in the ''Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Issues and Decision Memorandum for the Final Results of the 2010–2011 Administrative Review,'' dated concurrently with this notice (''Issues & Decision Memo''). A list of the issues raised by interested parties is attached to this notice as an Appendix. The Issues & Decision Memo is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov,* and it is available to all parties in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues & Decision Memo can be accessed directly on the Internet at *http://www.trade.gov/ia.* The signed Issues & Decision Memo and the electronic versions of the Issues & Decision Memo are identical in content.

Scope of the Order

The products covered by the order are all gauges of raw, pre-treated, or primed PET film, whether extruded or co-extruded.[7] PET film is classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Although the HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive. A full description of the scope of the order is contained in the Issues & Decision Memo.

Changes Since the Preliminary Results

Based on the comments received from the interested parties, we have made the following changes from the *Preliminary Results:*

1. We are including the reported reintroduced PET chip factor of production in the DuPont Group's normal value;
2. We are excluding the DuPont Group's reported billing adjustments from the calculation of U.S. net price;
3. We are correcting a clerical error in the calculation of surrogate selling, general, and administrative expenses, interest expenses, and profit for the DuPont Group and Green Packing;
4. Due to the changes in the dumping margins for DuPont Group, the rate calculated for the separate rate companies has also changed.

For a discussion of the issues, *see* the Issues & Decision Memo.

Non-Market Economy Country

The PRC has been treated as a non-market economy (''NME'') in every proceeding conducted by the Department. In accordance with section 771(18)(C)(i) of the Tariff Act of 1930, as amended (the ''Act''), any determination that a foreign country is an NME shall remain in effect until revoked by the administering authority. The Department has not revoked the PRC's status as an NME. Therefore, the Department continues to treat the PRC as an NME for purposes of these final results and, accordingly, applied the NME methodology.

Separate Rates

In proceedings involving NMEs, the Department maintains a rebuttable presumption that all companies within the NME are subject to government control and, therefore, should be assessed a single weighted-average dumping margin.[8] The Department's policy is to assign all exporters of merchandise subject to review in an NME country this single rate unless an exporter can demonstrate that it is sufficiently independent so as to be entitled to a separate rate.[9] The Department analyzes whether each entity exporting the merchandise under consideration is sufficiently independent under a test established in *Sparklers*[10] and further developed in

[1] *See Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Preliminary Results of Administrative Review; 2010–2011,* 77 FR 73428 (December 10, 2012), and accompanying Decision Memorandum (''*Preliminary Results*'').

[2] *See id.,* 77 FR at 73429.

[3] In the *Preliminary Results,* Tianjin Wanhua Co., Ltd. was erroneously referred to in the rate table as ''Tianjin Wanhua Co., Ltd. Sichuan'' The correct name of Tianjin Wanhua Co., Ltd. is shown in the rate table in this notice.

[4] In the *Preliminary Results,* Sichuan Dongfang Insulating Material Co., Ltd. was erroneously referred to in the rate table as ''Dongfang Insulating Material Co., Ltd.'' The correct name of Sichuan Dongfang Insulating Material Co., Ltd. is shown in the rate table in this notice.

[5] In the *Preliminary Results,* DuPont Teijin Films China Limited was erroneously referred to in the rate table as ''DuPont Teijin China Limited.'' The correct name of DuPont Teijin Films China Limited is shown in the rate table in this notice.

[6] The Department removed the rebuttal brief of Wanhua *et al.* from the administrative record because it contained untimely filed new factual information. The Department permitted the resubmission of a redacted version of the rebuttal brief, with the untimely factual information removed, on February 12, 2013.

[7] *See Polyethylene Terephthalate Film, Sheet, and Strip From Brazil, the People's Republic of China and the United Arab Emirates: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value for the United Arab Emirates,* 73 FR 66595 (November 10, 2008).

[8] *See, e.g., Polyethylene Terephthalate Film, Sheet, and Strip from the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 73 FR 55039, 55040 (September 24, 2008).

[9] *See Final Determination of Sales at Less Than Fair Value: Sparklers From the People's Republic of China,* 56 FR 20588, 20589 (May 6, 1991) (''*Sparklers*'').

[10] *See id.*

Silicon Carbide.[11] According to this separate rate test, the Department will assign a separate rate in NME proceedings if a respondent can demonstrate the absence of both *de jure* and *de facto* government control over its export activities. If, however, the Department determines that a company is wholly foreign owned, then a separate rate analysis is not necessary to determine whether that company is independent from government control and eligible for a separate rate.

In the *Preliminary Results,* the Department found that Dongfang, DuPont Group, Green Packing, Fuwei Films, and Wanhua demonstrated their eligibility for separate-rate status.[12] No party commented on these preliminary results. For the final results, the Department continues to find that the evidence placed on the record of this administrative review by Dongfang, DuPont Group, Green Packing, Fuwei Films, and Wanhua demonstrate both a *de jure* and *de facto* absence of government control and, therefore, are eligible for separate-rate status.

Rate for Non-Selected Companies

The statute and the Department's regulations do not address the establishment of a rate to be applied to individual respondents not selected for examination when the Department limits its examination in an administrative review pursuant to section 777A(c)(2) of the Act. Generally, the Department looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for guidance when calculating the rate for respondents which we did not examine in an administrative review. Section 735(c)(5)(A) of the Act articulates a preference that we are not to calculate an all-others rate using rates which are zero, *de minimis,* or based entirely on facts available. Accordingly, the Department's usual practice has been to average the weighted-average dumping margins for the selected companies, excluding rates that are zero, *de minimis,* or based entirely on facts available.[13] Section 735(c)(5)(B) of the Act also provides that, where all rates are zero, *de minimis,* or based entirely on facts available, we may use ''any reasonable method'' for assigning the all-others rate, including ''averaging the estimated weighted-average dumping margins determined for the exporters and producers individually investigated.''

In this instance, consistent with our practice, we have established a margin for the separate rate applicants based on the rate we calculated for the mandatory respondents whose rates were not zero, *de minimis,* or based entirely on facts available. Therefore, for the final results, we have excluded Green Packing's rate, and assigned DuPont's rate as the separate rate, *i.e.,* 12.80 percent.

Surrogate Country

In the *Preliminary Results,* we treated the PRC as an NME country and, therefore, we calculated normal value in accordance with section 773(c) of the Act. We selected Indonesia as the surrogate country, pursuant to section 773(c)(4) of the Act, because it is a significant producer of merchandise comparable to subject merchandise and is at a level of economic development comparable to the PRC.[14] For the final results of review, we have continued to treat the PRC as an NME country and have used the same primary surrogate country, Indonesia.

Final Results of the Review

The dumping margins for the POR are as follows:

Exporter	Weighted—average dumping margin (percent)
DuPont Teijin Films China Limited	12.80
Shaoxing Xiangyu Green Packing Co., Ltd	0.00
Fuwei Films (Shandong) Co., Ltd	12.80
Tianjin Wanhua Co., Ltd	12.80
Sichuan Dongfang Insulating Material Co., Ltd	12.80

Assessment Rates

Consistent with these final results, and pursuant to section 751(a)(2)(A) of the Act, and 19 CFR 351.212(b), the Department will direct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of the final results of review. Pursuant to 19 CFR 351.212(b)(1), the Department will calculate importer (or customer) -specific assessment rates based on the ratio of the total amount of the dumping margins calculated for the examined sales to the total entered value of those same sales.[15] The Department will instruct CBP to assess antidumping duties on all appropriate entries covered by this review if any importer-specific assessment rate is above *de minimis.*

The Department recently announced a refinement to its assessment practice in NME cases. Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the NME-wide rate. In addition, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the NME-wide rate.[16]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For the exporter listed above, the cash deposit rate will be established in the final results of this review (except, if the rate is zero or *de minimis, i.e.,* less than 0.5 percent, no cash deposit will be required for that company); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be that for the PRC-wide entity; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC

[11] *See Notice of Final Determination of Sales at Less Than Fair Value: Silicon Carbide From the People's Republic of China,* 59 FR 22585 (May 2, 1994) (''*Silicon Carbide*'').

[12] *See Preliminary Results,* and accompanying Decision Memorandum at 3.

[13] *See Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part,* 73 FR 52823, 52824 (September 11, 2008), and accompanying Issues and Decision Memorandum at Comment 16.

[14] *See Preliminary Results,* and accompanying Decision Memorandum at 7.

[15] In these final results, the Department applied the assessment rate calculation method adopted in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101 (February 14, 2012).

[16] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We will disclose the calculations performed within five days of the date of publication of this notice to parties in this proceeding in accordance with 19 CFR 351.224(b).

Notification to Importers Regarding The Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Orders

This notice also serves as a reminder to parties subject to administrative protective orders (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing this administrative review and notice in accordance with sections 751(a)(1) and 777(i) of the Act.

Dated: *June 5, 2013.*

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix—Issues & Decision Memorandum

I. General Issues

Issue 1: Respondent Selection
Issue 2: Surrogate Country Selection
Issue 3: Calculation of the Surrogate Financial Ratios
Issue 4: Calculation of a Separate Rate

II. Company-Specific Issues

Issue 5: Treatment of the DuPont Group's Reintroduced PET Chip
Issue 6: Calculation of the DuPont Group's U.S. Indirect Selling Ratio
Issue 7: Calculation of the DuPont Group's Foreign Brokerage and Handling Expenses
Issue 8: Calculation of the DuPont Group's Margin Using the Average-to-Transaction Method
Issue 9: The DuPont Group's Billing Adjustments
Issue 10: Green Packing's By-Product Offsets
Issue 11: Assessment Rate to Curwood

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–580–809]

Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Final Results of Antidumping Duty Administrative Review; 2010–2011

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On December 7, 2012, the Department of Commerce (the Department) published the preliminary results of the administrative review of the antidumping duty order on circular welded non-alloy steel pipe (CWP) from the Republic of Korea (Korea) for the period November 1, 2010, through October 31, 2011.[1] For these final results, we find that subject merchandise has been sold at less than normal value.

DATES: *Effective Date:* June 12, 2013.

FOR FURTHER INFORMATION CONTACT: Mary Kolberg or Jennifer Meek, AD/CVD Operations, Office 1, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–1785 or (202) 482–2778, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 7, 2012, the Department published the preliminary results of the administrative review of the antidumping duty order on CWP from Korea.[2]

On February 19, 2013, we received case briefs from Husteel Co., Ltd. (Husteel), Hyundai HYSCO (HYSCO), United States Steel Corporation, and Wheatland Tube Company. On February 28, 2013, we received rebuttal briefs from these four interested parties.

Scope of the Order

The merchandise subject to the order is circular welded non-alloy steel pipe and tube. For a full description of the scope of the order, see Issues and Decision Memorandum,[3] which is hereby adopted by this notice. The written description is dispositive.

Analysis of Comments Received

The comments received in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues raised and to which we have responded in the Issues and Decision Memorandum, is attached to this notice as an Appendix. The Issues and Decision Memorandum is a public document and is on file electronically *via* Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (IA ACCESS). Access to IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and is available to all parties in the Central Records Unit, Room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at *http://www.trade.gov/ia.* The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Changes From the Preliminary Results

Based on our analysis of the comments received from interested parties, we have changed our calculation methodology for Husteel's and HYSCO's dumping margins, by reallocating certain costs and revising the targeted dumping analysis, conversion factors, and general and administrative and financial expenses. *See* the Issues and Decision Memorandum and the company-specific calculation memoranda dated concurrently with this notice.

Final Results of the Review

As a result of this review, we determine that the following weighted-average dumping margins exist for the period November 1, 2010, through October 31, 2011:

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[1] *See Circular Welded Non-Alloy Steel Pipe From the Republic of Korea: Preliminary Results of Antidumping Duty Administrative Review; 2010–2011,* 77 FR 73015 (December 7, 2012) (*Preliminary Results*).

[2] *Id.*

[3] *See* Memorandum from Gary Taverman, Senior Advisor for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, entitled ''Issues and Decision Memorandum for the Administrative Review of the Antidumping Duty Order on Circular Welded Non-Alloy Steel Pipe from the Republic of Korea,'' (Issues and Decision Memorandum) dated concurrently with this notice.

Manufacturer/exporter	Weighted-average dumping margin (percent)
Husteel Co., Ltd	3.99
Hyundai HYSCO	0.80

Disclosure

We will disclose calculation memoranda used in our analysis to parties to these proceedings within five days of the date of the release of this notice pursuant to 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.212(b), the Department has determined, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries of subject merchandise in accordance with the final results of this review. The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review.

For assessment purposes, Husteel and HYSCO reported the name of the importer of record and the entered value for all of their sales to the United States during the period of review (POR). Accordingly, we calculated importer-specific *ad valorem* antidumping duty assessment rates on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales and the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). Where an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties in accordance with 19 CFR 351.106(c)(2).

The Department clarified its ''automatic assessment'' regulation on May 6, 2003. This clarification will apply to entries of subject merchandise during the POR produced by Husteel and HYSCO for which they did not know were destined for the United States. In such instances, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

Cash Deposit Requirements

The following deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered or withdrawn from warehouse, for consumption, on or after the date of publication as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for Husteel and HYSCO will be equal to the respective weighted-average dumping margin established in the final results of this review; (2) for merchandise exported by manufacturers or exporters not covered in this review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding in which that manufacturer or exporter participated; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the manufacturer of subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 4.80 percent, the ''all others'' rate established pursuant to a court decision.[4] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notifications

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of doubled antidumping duties.

This notice also serves as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return or destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

These final results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 5, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix

List of Issues Discussed in the Issues and Decision Memorandum

Targeted Dumping Allegation
Cost Reallocation
Conversion Factors
G&A
Date of Sale
Pipe Grade
Warranty Expense
Interest Revenue

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BILLING CODE 3510–DS–P

[4] *See Circular Welded Non-Alloy Steel Pipe From Korea: Notice of Final Court Decision and Amended Final Determination,* 60 FR 55833 (November 3, 1995).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–890]

Wooden Bedroom Furniture From the People's Republic of China: Final Results of Antidumping Duty Administrative Review; 2011

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On February 6, 2013, the Department of Commerce (the ''Department'') published the preliminary results of the administrative review (''AR'') of wooden bedroom furniture from the People's Republic of China (''PRC'') covering the period of review (''POR'') January 1, 2011 through December 31, 2011.[1] We gave interested parties an opportunity to comment on the *Preliminary Results.* After reviewing interested parties' comments and the information received, we made no changes for the final results of this review. In these final results of review we determined that six companies, including the two mandatory respondents,[2] failed to establish eligibility for separate-rate status and, thus, we treated these companies as part of the PRC-wide entity; six companies made no shipments of subject merchandise during the POR and will retain their separate-rate status, two companies are U.S. importers and, therefore, we rescinded the review of

[1] *See Wooden Bedroom Furniture From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2011,* 78 FR 8493 (February 6, 2013) (''*Preliminary Results*'').

[2] The two mandatory respondents are Shanghai Maoji Import and Export Corp. Ltd. (''Maoji''), and Dongguan Huansheng Furniture Co., Ltd. (''Huansheng'').

these companies, and three companies have demonstrated eligibility for separate-rate status and have been assigned antidumping duty margins. The final antidumping duty margins for this review are listed below in the ''Final Results of Review'' section of this notice.

DATES: *Effective Date:* June 12, 2013.

FOR FURTHER INFORMATION CONTACT: Patrick O'Connor, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–0989.

SUPPLEMENTARY INFORMATION:

Background

On February 6, 2013, the Department published its *Preliminary Results* of the AR of the antidumping order on wooden bedroom furniture from the PRC covering the period January 1, 2011, through December 31, 2011.

Analysis of the Comments Received

All issues raised in the case briefs are addressed in the memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order on Wooden Bedroom Furniture from the People's Republic of China'' (''I&D Memorandum''), which is dated concurrently with this notice and which is hereby adopted by this notice. A list of the issues addressed in the I&D Memorandum is appended to this notice. The I&D Memorandum is a public document and is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Services System (''IA ACCESS). Access to IA ACCESS is available to registered users at *http://iaaccess.trade.gov* and in the Central Records Unit of the main Commerce Building, Room 7046. In addition, a complete version of the I&D Memorandum is accessible on the Department's Web site at *http://www.trade.gov/ia/.* The signed I&D Memorandum and electronic version of the I&D Memorandum are identical in content.

Changes Since the Preliminary Results

We made no changes from the *Preliminary Results.*

Scope of the Order

The product covered by the order is wooden bedroom furniture, subject to certain exceptions. Imports of subject merchandise are currently classified under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings: 9403.50.9042, 9403.50.9045, 9403.50.9080, 9403.50.9041, 9403.60.8081, 9403.20.0018, 9403.90.8041, 7009.92.1000 or 7009.92.5000. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description in the Order remains dispositive.[3]

Final Partial Rescission

In the *Preliminary Results,* the Department stated that it intends to rescind the AR with respect to Foliot Furniture Pacific Inc. (''Foliot Pacific'') and Foliot Furniture Corporation (''Foliot Corporation'') because these companies were identified as U.S. importers and the Department does not conduct ARs of U.S. importers. No parties commented on our intent to rescind the AR with respect to these two companies. Because there is no information or argument on the record of the current AR that warrants reconsidering our intent to partially rescind this AR, we are rescinding this AR with respect to Foliot Pacific and Foliot Corporation.

Final Determination of No Shipments

As noted in the *Preliminary Results,* we determined that the following companies did not have any reviewable transactions during the POR: (1) Clearwise Company Limited (''Clearwise''); (2) Dongguan Yujia Furniture Co., Ltd. (''Yujia''); (3) Golden Well International (HK) Ltd. (''Golden Well''); (4) Hangzhou Cadman Trading Co., Ltd. (''Cadman''); (5) Yeh Brothers World Trade, Inc. (''Yeh Brothers''); and (6) Zhejiang Tianyi Scientific and Educational Equipment Co., Ltd. (''Zhejiang Tianyi'').[4] No parties commented on this issue, and we have not received any information that contradicts these companies' claims of no-shipments. We continue to find that these companies did not have shipments of subject merchandise during the POR. We will issue instructions to U.S. Customs and Border Protection (''CBP'') for any suspended entries under these companies' antidumping duty case numbers as noted below.

[3] For a complete description of the scope of the order, *see* I&D Memorandum.

[4] *See Preliminary Results,* 78 FR at 8494.

Final Results of Review

The Department has determined that the following dumping margins exist for the period January 1, 2011, through December 31, 2011:

Exporter	Weighted-average margin (percent)
Baigou Crafts Factory of Fengkai	41.75
Foliot Furniture Inc./Meubles Foliot Inc	41.75
Hualing Furniture (China) Co., Ltd.; Tony House Manufacture (China) Co., Ltd.; Buysell Investments Ltd.; and Tony House Industries Co., Ltd	41.75
PRC-wide Entity[5]	216.01

Assessment

The Department has determined, and CBP shall assess, antidumping duties on all appropriate entries covered by this AR. The Department intends to issue assessment instructions to CBP 15 days after the publication date of these final results of review. Pursuant to a recently announced refinement to the Department's assessment practice in NME cases, where we determined that an exporter under review had no shipments of the subject merchandise, any suspended entries under the exporter's antidumping case number (*i.e.,* entries suspended at the exporter's rate) will be liquidated at the PRC-wide rate. For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of these final results of this AR for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the companies listed in the ''Final Results of Review'' section above, the cash deposit rate will be the rate listed above for the company; (2) for Clearwise, Yujia, Golden Well, Cadman,

[5] The PRC-wide entity includes, among other companies: Shanghai Maoji Import and Export Corp. Ltd. Dongguan Huansheng Furniture Co., Ltd. Alexandre International Corp.; Southern Art Development Ltd.; Alexandre Furniture (Shenzhen) Co., Ltd.; Southern Art Furniture Factory; Billy Wood Industrial (Dong Guan) Co., Ltd.; Great Union Industrial (Dongguan) Co., Ltd.; Time Faith Ltd.; Dongying Huanghekou Furniture Industry Co., Ltd.; Sheng Jing Wood Products (Beijing) Co., Ltd.; and Telstar Enterprises Ltd.

Yeh Brothers, and Zhejiang Tianyi, which had no shipments, the cash deposit rate will remain unchanged from the rate assigned to these companies in the most recently completed review of the companies; (3) for previously investigated or reviewed PRC and non-PRC exporters who are not under review in this segment of the proceeding but who have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (4) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, including Maoji, Huansheng, Alexandre Furniture (Shenzhen) Co., Ltd.; Southern Art Furniture Factory; Billy Wood Industrial (Dong Guan) Co., Ltd.; Great Union Industrial (Dongguan) Co., Ltd.; Time Faith Ltd.; Dongying Huanghekou Furniture Industry Co., Ltd.; Sheng Jing Wood Products (Beijing) Co., Ltd.; and Telstar Enterprises Ltd., the cash deposit rate will be the PRC-wide rate of 216.01 percent; and (5) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of the antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This notice of the final results of the administrative review is issued and published in accordance with sections 751(a)(1) and 777(i) of the Act and 19 CFR 351.213(d)(4).

Dated: June 5, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix

Comment 1: Whether Maoji has Demonstrated Eligibility for Separate-Rate Status

Comment 2: The Appropriate Dumping Margin to Apply to Maoji as Part of the PRC-Wide Entity

Comment 3: Whether the Department Should Determine that Maoji's Suppliers are the Price Discriminators

Comment 4: Potential Evasion of Antidumping Duties on Huansheng's Subject Merchandise

[FR Doc. 2013–13987 Filed 6–11–13; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–964]

Seamless Refined Copper Pipe and Tube From the People's Republic of China: Final Results and Partial Revocation of 2010/11 Antidumping Duty Administrative Review

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: On August 7, 2012, the Department of Commerce (''Department'') published the preliminary results of the administrative review of the antidumping duty order on seamless refined copper pipe and tube (''copper pipe and tube'') from the People's Republic of China (''PRC''). The period of review (''POR'') is November 22, 2010 through October 31, 2011. Based on our analysis of the comments received, we have made no changes to the margin calculations for these final results. We continue to find that certain exporters have sold subject merchandise at less than normal value during the POR.

DATES: *Effective Date:* June 12, 2013.

FOR FURTHER INFORMATION CONTACT: Thomas Martin or Robert Bolling, AD/CVD Operations, Office 4, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3936, and (202) 482–3434, respectively.

SUPPLEMENTARY INFORMATION:

Background

On August 7, 2012, the Department published *Seamless Refined Copper Pipe and Tube From the People's Republic of China: Preliminary Results of the First Antidumping Duty Administrative Review, and Intent To Rescind in Part,* 77 FR 47030 (August 7, 2012) (''*Preliminary Results*'').

On August 21, 2012, Cerro Flow Products, LLC, Wieland Copper Products, LLC, Mueller Copper Tube Products, Inc., and Mueller Copper Tube Company, Inc. (collectively, ''Petitioners'') submitted additional surrogate value information for valuing factors of production. On August 27, 2012, Golden Dragon Precise Copper Tube Group, Inc. (''Golden Dragon'') also submitted additional surrogate value information for valuing factors of production. On August 27, 2012, the Department extended the deadline for filing comments on the *Preliminary Results* until September 13, 2012, and until September 18, 2012, for rebuttal comments. On September 5, 2012, Luvata Alltop (Zhongshan) Ltd. and Luvata Tube (Zhongshan) Ltd., (collectively ''Luvata'') filed comments on the *Preliminary Results.* The separate rate respondent Hong Kong Hailiang Metal Trading Limited, Zhejiang Hailiang Co., Ltd., and Shanghai Hailiang Copper Co., Ltd. (collectively ''Hailiang''), and Petitioners submitted case briefs with the Department on September 13, 2012. On September 17, 2012, the Department extended the deadline for rebuttal briefs until September 21, 2012. On September 21, 2012, Petitioners and Golden Dragon filed rebuttal briefs.

On April 23, 2013, the Department requested additional factual documentation from Golden Dragon,[1] which was submitted on April 24, 2013. On May 2, 2013, in response to an opportunity to comment from the Department, Petitioners and Golden Dragon submitted comments in response to Golden Dragon's April 24, 2013, factual submission. On May 6, 2013, Petitioners and Golden Dragon submitted rebuttal comments.

The Department's original deadline for this final determination was December 5, 2012. As explained in the memorandum from the Assistant Secretary for Import Administration, the Department exercised its discretion to toll deadlines for the duration of the closure of the Federal Government from October 29, through October 30, 2012.

[1] *See* Memorandum from Christian Marsh to the File, ''Telephone Conversation with Counsel for Golden Dragon Precise Copper Tube Group, Inc. *et al.,*'' dated April 23, 2013.

Thus, the final results were tolled by two days until December 7, 2012.[2] On November 29, 2012, the Department extended the final results 60 days until February 5, 2013.[3] On January 24, 2013, the Department extended the final results 90 days until May 6, 2013.[4] On April 30, 2013, the Department extended the final results 30 days until June 5, 2013.[5]

Scope of the Order

For the purpose of the order, the products covered are all seamless circular refined copper pipes and tubes.[6] The products subject to the order are currently classifiable under subheadings 7411.10.1030 and 7411.10.1090 of the Harmonized Tariff Schedule of the United States (''HTSUS''). Products subject to the order may also enter under HTSUS subheadings 7407.10.1500, 7419.99.5050, 8415.90.8065, and 8415.90.8085. Although the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of the order is dispositive.[7]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this review are addressed in the Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Import Administration, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of Seamless Refined Copper Pipe and Tube from the People's Republic of China; 2010–2011,'' dated June 5, 2013 (''Issues and Decision Memorandum''), which is hereby adopted by this notice. A list of the issues which parties raised and to which we respond in the Issues and Decision Memorandum is attached to this notice as an Appendix. The Issues and Decision Memorandum, which is a public document, is on file electronically via Import Administration's Antidumping and Countervailing Duty Centralized Electronic Service System (''IA ACCESS''). IA ACCESS is available to registered users at *http://iaaccess.trade.gov*, and is available to all parties in the Central Records Unit, main Commerce building, Room 7046. In addition, a complete version of the Issues and Decision Memorandum is accessible on the Department's Web site at *http://www.trade.gov/ia.* The signed Issues and Decision Memorandum and electronic versions of the memorandum are identical in content.

Changes Since the Preliminary Results

There have been no changes since *Preliminary Results.*

Period of Review

The POR is November 22, 2010, through October 31, 2011.

Partial Rescission of Review

Petitioners timely requested an administrative review for Golden Dragon Holding (Hong Kong) International Co., Ltd., Hong Kong GD Trading Co., Ltd., Sinochem Ningbo Import & Export Co., Ltd., and Sinochem Ningbo Ltd., companies which do not have a separate rate, and then timely withdrew their requests for review of the above-mentioned companies.[8] Because these companies have not established their eligibility for a separate rate, they would be considered part of the PRC-wide entity. In the *Preliminary Results,* we stated that we intended to rescind the administrative review with respect to these companies in the final results if the PRC-wide entity is not reviewed.[9] Because the PRC-wide entity is not under review for the final results of this administrative review, we are rescinding the administrative review for the above-mentioned companies for which we received a timely withdrawal of the request for administrative review in accordance with 19 CFR 351.213(d)(1).

Petitioners also timely requested an administrative review, then timely withdrew their requests for the following companies that have previously established their eligibility for separate rate: Luvata Alltop (Zhongshan) Ltd., Luvata Tube (Zhongshan) Ltd., Ningbo Jintian Copper Tube Co., Ltd., Zhejiang Jiahe Pipes Inc., and Zhejiang Naile Copper Co., Ltd.[10] Because the requests for administrative reviews for these companies were timely withdrawn, we are rescinding the administrative review for these companies in accordance with 19 CFR 351.213(d)(1).

Final Results of the Review

We determine that the following weighted-average dumping margins exist for the POR:

Exporter	Margin (percentage)
Golden Dragon Precise Copper Tube Group, Inc	0.00
Hong Kong Hailiang Metal Trading Limited, Zhejiang Hailiang Co., Ltd., and Shanghai Hailiang Copper Co., Ltd	60.85

Disclosure

The Department intends to disclose calculations performed for these final results to the parties within five days of the date of the public announcement of the results of this review in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b), the Department will determine, and U.S. Customs and Border Protection (''CBP'') shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review.

For each respondent whose weighted-average dumping margin in these final results is not zero or *de minimis* (*i.e.*, less than 0.5 percent), the Department has calculated importer-specific assessment rates. Because we do not have entered values for all U.S. sales to a particular importer, we are calculating a per-unit assessment rate by aggregating the amount of dumping for all U.S. sales to that importer and dividing this amount by the total

[2] *See* Memorandum to the Record from Paul Piquado, AS for Import Administration, regarding ''Tolling of Administrative Deadlines As a Result of the Government Closure During the Recent Hurricane,'' dated October 31, 2012.

[3] *See* Memorandum to Christian Marsh regarding ''Seamless Refined Copper Pipe and Tube from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated November 29, 2012.

[4] *See* Memorandum to Christian Marsh regarding ''Seamless Refined Copper Pipe and Tube from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated January 24, 2013.

[5] *See* Memorandum to Christian Marsh regarding ''Seamless Refined Copper Pipe and Tube from the People's Republic of China: Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated April 30, 2013.

[6] *See* Issues and Decision Memorandum.

[7] For a complete description of the scope of the order, *see Seamless Refined Copper Pipe and Tube From Mexico and the People's Republic of China: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value From Mexico,* 75 FR 71070 (November 22, 2010).

[8] *See* Petitioners' letter entitled, ''Seamless Refined Copper Pipe and Tube From the People's Republic of China: Withdrawal of Request for Antidumping Administrative Reviews,'' dated February 6, 2012.

[9] *See Preliminary Results,* 77 FR at 47031.

[10] *See* Petitioners' letter entitled, ''Seamless Refined Copper Pipe and Tube From the People's Republic of China: Withdrawal of Request for Antidumping Administrative Reviews,'' dated February 6, 2012. In the *Preliminary Results,* 77 FR at 47301, we inadvertently identified these companies as not having established their eligibility for a separate rate.

quantity sold to that importer.[11] Where an exporter's weighted-average dumping margin is zero or *de minimis,* or an importer-specific *ad valorem* rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties. To determine whether an importer-specific, *ad valorem* assessment rates is *de minimis,* in accordance with the requirement set forth in 19 CFR 351.106(c)(2), we calculated importer-specific *ad valorem* rates as the amount of dumping for all U.S. sales to an importer divided by the estimated entered value of the same sales. We will instruct CBP to liquidate entries of subject merchandise exported by the PRC-wide entity at an *ad valorem* assessment rate equal to the weighted-average dumping margin assigned to the PRC-wide entity.

The Department announced a refinement to its assessment practice in non-market economy cases.[12] Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales databases submitted by companies individually examined during this review, the Department will instruct CBP to liquidate such entries at the rate for the PRC-wide entity. In addition, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number (*i.e.,* at that exporter's rate) will be liquidated at the rate for the PRC-wide entity.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided for by section 751(a)(2)(C) of the Act: (1) For the exporters listed above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review (except, if the rate is zero or *de minimis,* then the cash deposit rate will be zero for that exporter); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be equal to 60.85 percent, the rate for the PRC-wide entity;[13] and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

The Department is issuing and publishing these final results of administrative review in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: June 5, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

Appendix—Issues and Decision Memorandum

Comment 1: Whether the Department should rescind the administrative review with respect to Luvata

Comment 2: Whether Golden Dragon's U.S. sales listing is accurate

Comment 3: Whether the Department should make an adjustment to Golden Dragon's reported U.S. prices

Comment 4: Whether the Department should use the financial statement of Kobelco or Furukawa.

Comment 5: Whether the Department should use a different rate for Hailiang as a non-examined, separate rate respondent

[FR Doc. 2013–13965 Filed 6–11–13; 8:45 am]

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[11] *See, e.g., Certain Cased Pencils From the People's Republic of China: Final Results of the Antidumping Duty Administrative Review,* 76 FR 27988, 27989 (May 13, 2011).

[12] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[13] *See Seamless Refined Copper Pipe and Tube From the People's Republic of China: Final Determination of Sales at Less Than Fair Value,* 75 FR 60725, 60729 (October 1, 2010).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–557–815, A–549–830, A–552–816]

Welded Stainless Pressure Pipe From Malaysia, Thailand, and the Socialist Republic of Vietnam: Initiation of Antidumping Duty Investigations

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

DATES: *Effective Date:* June 12, 2013.

FOR FURTHER INFORMATION CONTACT: Edythe Artman (Malaysia), Victoria Cho (Thailand), or Fred Baker (Vietnam), at (202) 482–3931, (202) 482–5075, or at (202) 482–2924, respectively, AD/CVD Operations, Office 7, Import Administration, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

The Petitions

On May 16, 2013, the Department of Commerce (the Department) received antidumping duty (AD) Petitions concerning imports of welded stainless pressure pipe (welded stainless pipe) from Malaysia, Thailand, and the Socialist Republic of Vietnam (Vietnam) filed in proper form on behalf of Bristol Metals, LLC, Felker Brothers Corp., and Outokumpu Stainless Pipe, Inc., (collectively, Petitioners).[1] Petitioners are domestic producers of welded stainless pipe. On May 21, 2013, the Department requested additional information and clarification of certain areas of the Petitions. Petitioners filed responses to these requests on May 24, 2013.[2] On May 29, 2013, the Department requested additional information and clarification of certain

[1] *See* Petitions for the Imposition of Antidumping Duties on Imports of Welded Stainless Pressure Pipe from Malaysia, Thailand, and Vietnam, dated May 16, 2013 (Petitions).

[2] *See* Supplement to the Malaysia Petition, dated May 24, 2013 (Malaysia Supplement), Supplement to the Thailand Petition, dated May 24, 2013 (Thailand Supplement); and Supplement to the Vietnam Petition, dated May 24, 2013 (Vietnam Supplement).

areas of the Petitions. Petitioners filed responses to these requests on May 30, 2013.[3]

In accordance with section 732(b) of the Tariff Act of 1930, as amended (the Act), Petitioners allege that imports of welded stainless pipe from Malaysia, Thailand, and Vietnam are being, or are likely to be, sold in the United States at less than fair value within the meaning of section 731 of the Act and that such imports are materially injuring, or threatening material injury to, an industry in the United States. Also, consistent with section 732(b)(1) of the Act, the Petitions are accompanied by information reasonably available to Petitioners supporting their allegations.

The Department finds that Petitioners filed these Petitions on behalf of the domestic industry because Petitioners are interested parties as defined in section 771(9)(C) of the Act. The Department also finds that Petitioners have demonstrated sufficient industry support with respect to the initiation of the AD investigations that Petitioners are requesting. *See* the ''Determination of Industry Support for the Petitions'' section below.

Periods of Investigation

Because the Petitions were filed on May 16, 2013, the period of investigation (POI) for the Vietnam investigation is October 1, 2012, through March 31, 2013. The POI for the Malaysia and Thailand investigations is April 1, 2012, through March 31, 2013.[4]

Scope of the Investigations

The product covered by these investigations is welded stainless pipe from Malaysia, Thailand, and Vietnam. For a full description of the scope of the investigations, *see* the ''Scope of the Investigations,'' in Appendix I of this notice.

Comments on Scope of Investigations

During our review of the Petitions, we discussed the scope with Petitioners to ensure that it is an accurate reflection of the product for which the domestic industry is seeking relief. Moreover, as discussed in the preamble to the regulations (*Antidumping Duties; Countervailing Duties; Final Rule,* 62 FR 27296, 27323 (May 19, 1997)), we are setting aside a period for interested parties to raise issues regarding product coverage. The Department encourages all interested parties to submit such comments by June 25, 2013, 5:00 p.m. Eastern Daylight Time, 20 calendar days from the signature date of this notice. All comments must be filed on the records of the Malaysia, Thailand, and Vietnam AD investigations. All comments and submissions to the Department must be filed electronically using Import Administration's Antidumping Countervailing Duty Centralized Electronic Service System (IA ACCESS).[5] An electronically filed document must be received successfully in its entirety by the Department's electronic records system, IA ACCESS, by the time and date noted above. Documents excepted from the electronic submission requirements must be filed manually (*i.e.,* in paper form) with Import Administration's APO/Dockets Unit, Room 1870, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, and stamped with the date and time of receipt by the deadline noted above.

The period of scope comments is intended to provide the Department with ample opportunity to consider all comments and to consult with parties prior to the issuance of the preliminary determinations.

Comments on Product Characteristics for Antidumping Questionnaires

The Department requests comments from interested parties regarding the appropriate physical characteristics of welded stainless pipe to be reported in response to the Department's AD questionnaires. This information will be used to identify the key physical characteristics of the subject merchandise in order to report the relevant factors and costs of production accurately as well as to develop appropriate product-comparison criteria.

Interested parties may provide any information or comments that they feel are relevant to the development of an accurate list of physical characteristics. Specifically, they may provide comments as to which characteristics are appropriate to use as: (1) General product characteristics and (2) product-comparison criteria. We note that it is not always appropriate to use all product characteristics as product-comparison criteria. We base product-comparison criteria on meaningful commercial differences among products. In other words, while there may be some physical product characteristics utilized by manufacturers to describe welded stainless pipe, it may be that only a select few product characteristics take into account commercially meaningful physical characteristics. In addition, interested parties may comment on the order in which the physical characteristics should be used in matching products. Generally, the Department attempts to list the most important physical characteristics first and the least important characteristics last.

In order to consider the suggestions of interested parties in developing and issuing the AD questionnaires, we must receive comments on product characteristics by June 25, 2013.

Rebuttal comments must be received by July 2, 2013. All comments and submissions to the Department must be filed electronically using IA ACCESS, as referenced above.

Determination of Industry Support for the Petitions

Section 732(b)(1) of the Act requires that a petition be filed on behalf of the domestic industry. Section 732(c)(4)(A) of the Act provides that a petition meets this requirement if the domestic producers or workers who support the petition account for: (i) At least 25 percent of the total production of the domestic like product; and (ii) more than 50 percent of the production of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the petition. Moreover, section 732(c)(4)(D) of the Act provides that, if the petition does not establish support of domestic producers or workers accounting for more than 50 percent of the total production of the domestic like product, the Department shall: (i) Poll the industry or rely on other information in order to determine if there is support for the petition, as required by subparagraph (A); or (ii) determine industry support using a statistically valid sampling method to poll the industry.

Section 771(4)(A) of the Act defines the ''industry'' as the producers as a whole of a domestic like product. Thus, to determine whether a petition has the requisite industry support, the statute directs the Department to look to producers and workers who produce the domestic like product. The International Trade Commission (ITC), which is responsible for determining whether ''the domestic industry'' has been injured, must also determine what constitutes a domestic like product in order to define the industry. While both the Department and the ITC must apply

[3] *See* Second General Issues Supplement to the Petitions, dated May 30, 2013 (Second Supplement).

[4] *See* 19 CFR 351.204(b)(1).

[5] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011) for details of the Department's electronic filing requirements, which went into effect on August 5, 2011. Information on help using IA ACCESS can be found at *https://iaaccess.trade.gov/help.aspx* and a handbook can be found at *https://iaaccess.trade.gov/help/Handbook%20on%20Electronic%20Filling%20Procedures.pdf.*

the same statutory definition regarding the domestic like product,[6] they do so for different purposes and pursuant to a separate and distinct authority. In addition, the Department's determination is subject to limitations of time and information. Although this may result in different definitions of the like product, such differences do not render the decision of either agency contrary to law.[7]

Section 771(10) of the Act defines the domestic like product as ''a product which is like, or in the absence of like, most similar in characteristics and uses with, the article subject to an investigation under this title.'' Thus, the reference point from which the domestic like product analysis begins is ''the article subject to an investigation'' (*i.e.,* the class or kind of merchandise to be investigated, which normally will be the scope as defined in the petition).

With regard to the domestic like product, Petitioners do not offer a definition of domestic like product distinct from the scope of the investigations. Based on our analysis of the information submitted on the record, we have determined that welded stainless pipe constitutes a single domestic like product and we have analyzed industry support in terms of that domestic like product.[8]

In determining whether Petitioners have standing under section 732(c)(4)(A) of the Act, we considered the industry support data contained in the Petitions with reference to the domestic like product as defined in the ''Scope of Investigations,'' in Appendix I of this notice. To establish industry support, Petitioners provided their shipments of the domestic like product in 2012, and compared their shipments to the estimated total shipments of the domestic like product for the entire domestic industry.[9] Because total industry production data for the domestic like product for 2012 is not reasonably available and Petitioners have established that shipments are a reasonable proxy for production data,[10] we have relied upon the shipment data provided by Petitioners for purposes of measuring industry support.[11]

Our review of the data provided in the Petitions, supplemental submissions, and other information readily available to the Department indicates that Petitioners have established industry support. First, the Petitions established support from domestic producers accounting for more than 50 percent of the total shipments [12] of the domestic like product and, as such, the Department is not required to take further action in order to evaluate industry support (*e.g.,* polling).[13] Second, the domestic producers have met the statutory criteria for industry support under section 732(c)(4)(A)(i) of the Act because the domestic producers who support the Petitions account for at least 25 percent of the total shipments of the domestic like product.[14] Finally, the domestic producers have met the statutory criteria for industry support under section 732(c)(4)(A)(ii) of the Act because the domestic producers who support the Petitions account for more than 50 percent of the shipments of the domestic like product produced by that portion of the industry expressing support for, or opposition to, the Petitions.[15] Accordingly, the Department determines that the Petitions were filed on behalf of the domestic industry within the meaning of section 732(b)(1) of the Act.[16]

The Department finds that Petitioners filed the Petitions on behalf of the domestic industry because they are interested parties as defined in section 771(9)(C) of the Act and they have demonstrated sufficient industry support with respect to the antidumping duty investigations they are requesting the Department initiate.[17]

Allegations and Evidence of Material Injury and Causation

Petitioners allege that the U.S. industry producing the domestic like product is being materially injured, or is threatened with material injury, by reason of the imports of the subject merchandise sold at less than normal value (NV). In addition, Petitioners allege that subject imports exceed the negligibility threshold provided for under section 771(24)(A) of the Act.[18]

Petitioners contend that the industry's injured condition is illustrated by reduced market share; increased market penetration; underselling and price depression or suppression; lost sales and revenues; declining production and shipments and reduced capacity utilization; increased inventories; and decline in financial performance.[19] We have assessed the allegations and supporting evidence regarding material injury, threat of material injury, and causation, and we have determined that these allegations are properly supported by adequate evidence and meet the statutory requirements for initiation.[20]

Allegations of Sales at Less Than Fair Value

The following is a description of the allegations of sales at less-than-fair-value upon which the Department based its decision to initiate investigations of imports of welded stainless pipe from Malaysia, Thailand, and Vietnam. The sources of data for the deductions and adjustments relating to U.S. price and NV are discussed in greater detail in the Malaysia Initiation Checklist, Thailand Initiation Checklist, and Vietnam Initiation Checklist.

Export Price

Malaysia

Petitioners calculated U.S. price based on an average unit value (AUV) compiled from U.S. Department of Commerce import statistics, obtained through ITC's Dataweb, for the POI.

[6] *See* section 771(10) of the Act.

[7] *See USEC, Inc.* v. *United States,* 132 F. Supp. 2d 1, 8 (CIT 2001) (citing *Algoma Steel Corp., Ltd. v. United States,* 688 F. Supp. 639, 644 (CIT 1988), *aff'd* 865 F.2d 240 (Fed. Cir. 1989)).

[8] For a discussion of the domestic like product analysis in these cases, *see* Antidumping Duty Investigation Initiation Checklist: Welded Stainless Pressure Pipe from Malaysia (Malaysia Checklist), Antidumping Duty Investigation Initiation Checklist: Welded Stainless Pressure Pipe from Thailand (Thailand Checklist), and Antidumping Duty Investigation Initiation Checklist: Welded Stainless Pressure Pipe from Vietnam (Vietnam Checklist) at Attachment II, Analysis of Industry Support for the Petitions Covering Welded Stainless Pressure Pipe (Attachment II). These checklists are dated concurrently with this notice and on file electronically via IA ACCESS. Access to documents filed via IA ACCESS is also available in the Central Records Unit (CRU), Room 7046 of the main Department of Commerce building.

[9] *See* Volume I of the Petitions, at Exhibit I–3; Malaysia Supplement at 1–3; Thailand Supplement at 1–3; Vietnam Supplement at 1–3; and Second Supplement at 1–2.

[10] *See* Malaysia Supplement, Thailand Supplement, and Vietnam Supplement, at 2.

[11] For further discussion, *see* Malaysia Checklist, Thailand Checklist, and Vietnam Checklist, at Attachment II.

[12] As mentioned above, Petitioners have established that shipments are a reasonable proxy for production data. Section 351.203(e)(1) of the Department's regulations states ''production levels may be established by reference to alternative data that the Secretary determines to be indicative of production levels.''

[13] *See* section 732(c)(4)(D) of the Act and Malaysia Checklist, Thailand Checklist, and Vietnam Checklist, at Attachment II.

[14] *See* Malaysia Checklist, Thailand Checklist, and Vietnam Checklist, at Attachment II.

[15] *See id.*

[16] *Id.*

[17] *Id.*

[18] *See* Malaysia Supplement, at 4 and Exhibit S8; Thailand Supplement, at 4 and Exhibit S8; and Vietnam Supplement, at 4 and Exhibit S8.

[19] *See* Volume II of the Petitions, at 1, 5–10, 12 and Exhibits II–1 and II–2; *see also* Malaysia Supplement, at 4 and Exhibit S7; Thailand Supplement, at 4 and Exhibit S7; and Vietnam Supplement, at 4 and Exhibit S7.

[20] *See* Malaysia Initiation Checklist at Attachment III, Analysis of Allegations and Evidence of Material Injury and Causation for the Petitions Covering Welded Stainless Pressure Pipe from Malaysia, Thailand, and Vietnam (Attachment III); Thailand Initiation Checklist at Attachment III; and Vietnam Initiation Checklist at Attachment III.

Petitioners used imports from Malaysia under Harmonized Tariff Schedule of the United States (HTSUS) subheading 7306.40.5064 to calculate an AUV because this subheading most closely corresponds to the products for which Petitioners obtained home market prices. Petitioners made no deductions to the AUV they calculated.

Thailand

Petitioners calculated U.S. price based on an AUV compiled from U.S. Department of Commerce import statistics, obtained through ITC's Dataweb, for the POI. Petitioners used imports from Thailand under HTSUS subheading 7306.40.5064 to calculate an AUV because this subheading most closely corresponds to the products for which Petitioners obtained home market prices. Petitioners made no deductions to the AUV they calculated. Because the NV for Thailand was calculated on the basis of net tons, Petitioners converted the AUV to an AUV per net ton.

Vietnam

Petitioners calculated U.S. price based on an AUV compiled from U.S. Department of Commerce import statistics, obtained through ITC's Dataweb, for the POI. Petitioners used imports from Vietnam under HTSUS subheading 7306.40.5064 to calculate an AUV because this subheading most closely corresponds to the products for which Petitioners calculated a normal value.

Normal Value

Malaysia

Petitioners based NV on reasonably available home market prices of the foreign like product produced and offered for sale in Malaysia by a Malaysia producer of welded stainless pipe.[21]

According to Petitioners, packing charges were included in the prices in both the home market and in the United States, but because home market packing is not significantly different than packing for export to the U.S. market, no adjustment was made for market differences in packing.

Thailand

Petitioners based NV on home market prices of the foreign like product produced and offered for sale in Thailand by a Thai producer of welded stainless pipe.[22]

According to Petitioners, packing charges were included in the prices in both the home market and in the United States, but because home market packing is not significantly different than packing for export to the U.S. market, no adjustment was made for market differences in packing. Petitioners made no other adjustments to NV.

Vietnam

Petitioners state that the Department has long treated Vietnam as a non-market economy (NME) country.[23] In accordance with section 771(18)(C)(i) of the Act, the presumption of NME status remains in effect until revoked by the Department. The presumption of NME status for Vietnam has not been revoked by the Department and, therefore, remains in effect for purposes of the initiation of this investigation. Accordingly, the NV of the product is appropriately based on factors of production (FOPs) valued in a surrogate market-economy country in accordance with section 773(c) of the Act. In the course of this investigation, all parties, including the public, will have the opportunity to provide relevant information related to the issues of Vietnam's NME status and the granting of separate rates to individual exporters.

Petitioners claim that India is an appropriate surrogate country because it is a market economy that is at a comparable level of economic development to Vietnam. Petitioners also believe that India is a significant producer of merchandise under consideration.[24]

Based on the information provided by Petitioners, we believe it is appropriate to use India as a surrogate country for initiation purposes. Interested parties will have the opportunity to submit comments regarding surrogate country selection and will be provided an opportunity to submit publicly available information to value FOPs within 40 days before the scheduled date of the preliminary determination.[25]

Factors of Production

Petitioners based factors of production usage on the consumption rates of Bristol Metals, LLC. Petitioners assert that the experience of Bristol Metals is appropriate for comparison to producers in Vietnam because the production process is the same all over the world. It consists of slowly and carefully forming and welding high-end stainless steel strip into a pipe of the appropriate size.[26]

Valuation of Raw Materials and By-Product

Petitioners valued steel coils and the by-product offset based on reasonably available, public surrogate country data, specifically, Indian import statistics from the Global Trade Atlas (GTA).[27] Petitioners excluded from these import statistics values from countries previously determined by the Department to be NME countries. Petitioners also excluded imports from Indonesia, the Republic of Korea and Thailand, as the Department has previously excluded imports from these countries because they maintain broadly available, non-industry-specific export subsidies. In addition, Petitioners also excluded certain imports that were labeled as originating from an unspecified country because it is the Department's normal practice to exclude certain imports that were labeled as originating from an ''unspecified'' country from the surrogate values because the Department cannot be certain that they were not from either an NME country or a country with generally available export subsidies.

Valuation of Direct and Indirect Labor

Petitioners determined labor costs using the labor consumption rates derived from one U.S. producer.[28] Petitioners valued labor using a 2005 India wage rate from LABORSTA, a labor database compiled by the International Labor Organization (ILO) and disseminated in Chapter 6A of the ILO Yearbook of Labor Statistics. Petitioners adjusted this rate for inflation.[29]

Valuation of Energy

Petitioners determined electricity costs using the electricity consumption rates, in kilowatt hours, derived from one U.S. producer's experience. Petitioners assigned a value to those consumption rates using the Indian electricity rate reported by the Central Electric Authority of the Government of India.[30]

In addition to electricity, Petitioners also included costs for the energy inputs hydrogen, helium, and argon. They valued these factors using data from the

[21] *See* Malaysia Initiation Checklist.

[22] *See* Thailand Initiation Checklist.

[23] *See* Volume IV of the Petitions, at 1.

[24] *See id.,* at 1–2.

[25] *See* 19 CFR 351.301(c)(3)(i). Note that this is the revised regulation published on April 1, 2013. *See http://www.gpo.gov/fdsys/pkg/CFR-2013-title19-vol3/html/CFR-2013-title19-vol3.htm.*

[26] *See* Vietnam Supplement, at A–1 to A–2.

[27] *See* Volume IV of the Petitions, at 3–4 and Exhibit IV–3 and the Vietnam Supplement, at Exhibit IV–3 (Revised).

[28] *See* Volume IV of the Petitions, at 5 and Exhibit IV–2.

[29] *See* Volume IV of the Petitions, at 5 and Exhibit IV–5 and Vietnam Supplement, at A–3.

[30] *See* Volume IV of the Petitions at 5.

GTA for the period September 2012 through February 2013, the most recent six-month period for which data were available.[31]

Packing Materials

Petitioners made no adjustment for packing because they believed packing costs do not differ significantly between the two markets, and it would thus have no effect on the margin.[32]

Valuation of Factory Overhead, Selling, General and Administrative Expenses, and Profit

Petitioners calculated financial ratios (*i.e.,* manufacturing overhead, SG&A, and profit) using the financial statement of Ratnamani Metals & Tube, an Indian producer of comparable merchandise for the year ending March 31, 2012.[33]

Fair Value Comparisons

Based on the data provided by Petitioners, there is reason to believe that imports of welded stainless pipe from Malaysia, Thailand, and Vietnam are being, or are likely to be, sold in the United States at less than fair value. Based on comparisons of EP to NV in accordance with section 773(a)(1) of the Act, the estimated dumping margins for welded stainless pipe from Malaysia range from 22.67 percent to 22.73 percent.[34] Based on comparisons of EP to NV in accordance with section 773(a)(1) of the Act, the estimated dumping margins for welded stainless pipe from Thailand range from 23.77 percent to 24.01 percent.[35] Based on comparisons of EP to NV in accordance with section 773(c) of the Act, the estimated dumping margins for welded stainless pipe from Vietnam range from 89.4 percent to 90.8 percent.[36]

Initiation of Antidumping Duty Investigations

Based upon the examination of the Petitions on welded stainless pipe from Malaysia, Thailand and Vietnam, we find that the Petitions meet the requirements of section 732 of the Act. Therefore, we are initiating AD investigations to determine whether imports of welded stainless pipe from Malaysia, Thailand, and Vietnam are being, or are likely to be, sold in the United States at less than fair value. In accordance with section 733(b)(1)(A) of the Act and 19 CFR 351.205(b)(1), unless postponed, we will make our preliminary determinations no later than 140 days after the date of this initiation.

Respondent Selection

With respect to Malaysia, Petitioners name seven companies as producers/exporters of welded stainless pipe from Malaysia: Amalgamated Industrial Steel Berbad; Kanzen Tetsu Sdn. Bhd.; Tan Timur Stainless Steel Dan Copper Sdn. Bhd.; Prestar Precision Tube Sdn. Bhd.; Pantech Stainless & Alloy Industries Sdn. Bhd.; K. Seng Seng Corporation Berhad; and Superinox Pipe Industry Sdn. Bhd.[37]

Following standard practice in AD investigations involving market economy countries, in the event the Department determines that the number of known exporters or producers for this investigation is large, the Department may select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports of welded stainless pipe from Malaysia. We intend to release the CBP data under Administrative Protective Order (APO) to all parties with access to information protected by APO within five days of publication of this **Federal Register** notice.

We intend to make our decision regarding respondent selection within 20 days of publication of this notice. The Department invites comments regarding the CBP data and respondent selection within seven days of publication of this **Federal Register** notice for Malaysia, Thailand, and Vietnam.[38]

As to Thailand and Vietnam, although the Department normally relies on import data from CBP to select a limited number of exporters/producers for individual examination in AD investigations, these Petitions name only one company as a producer and/or exporter of welded stainless pipe from Vietnam (Sonha) and two companies as producers and/or exporters of welded stainless pipe from Thailand (Thai-German Products Public Co., Ltd. and Toyo Millennium). We currently know of no additional exporters or producers of subject merchandise from these countries. Accordingly, the Department intends to examine all known exporters of welded stainless steel pipe from Thailand and Vietnam.

Separate Rates

In order to obtain separate-rate status in an NME investigation, exporters and producers must submit a separate-rate status application.[39] The specific requirements for submitting the separate-rate application in the Vietnam investigation are outlined in detail in the application itself, which will be available on the Department's Web site at *http://trade.gov/ia/ia-highlights-and-news.html* on the date of publication of this initiation notice in the **Federal Register**. The separate-rate application will be due 60 days after publication of this initiation notice. For exporters and producers who submit a separate-rate status application and have been selected as mandatory respondents, these exporters and producers will no longer be eligible for consideration for separate rate status unless they respond to all parts of the questionnaire as mandatory respondents. The Department requires that Vietnam respondents submit a response to the separate-rate application by the deadline in order to receive consideration for separate-rate status.

Use of Combination Rates

The Department will calculate combination rates for certain respondents that are eligible for a separate rate in an NME investigation. The Separate Rates and Combination Rates Bulletin states:

> [w]hile continuing the practice of assigning separate rates only to exporters, all separate rates that the Department will now assign in its NME Investigation will be specific to those producers that supplied the exporter during the period of investigation. Note, however, that one rate is calculated for the exporter and all of the producers which supplied subject merchandise to it during the period of investigation. This practice applies both to mandatory respondents receiving an individually calculated separate rate as well as the pool of non-investigated firms receiving the weighted-average of the individually calculated rates. This practice is referred to as the application of ''combination rates'' because such rates apply to specific combinations of exporters and one or more producers. The cash-deposit rate assigned to an exporter will apply only to merchandise both exported by the firm in question *and* produced by a firm that supplied the exporter during the period of investigation.[40]

[31] *See id.,* at Exhibit IV–2; *see also* Vietnam Supplement, at and Exhibit IV–3 (Revised).

[32] *See* Vietnam Supplement, at A–2.

[33] *See* Volume IV of the Petitions, at 5 and Exhibit IV–6; *see also* Vietnam Supplement, at Exhibit IV–6 (Revised).

[34] *See* Malaysia Initiation Checklist.

[35] *See* Thailand Initiation Checklist.

[36] *See* Vietnam Initiation Checklist.

[37] *See* the Petitions at Volume I, Exhibit I–5.

[38] *See Bottom Mount Combination Refrigerator-Freezers From the Republic of Korea and Mexico: Initiation of Antidumping Duty Investigations,* 76 FR 23281, 23285 (April 26, 2011).

[39] *See* Policy Bulletin 05.1: Separate-Rates Practice and Application of Combination Rates in Antidumping Investigation involving Non-Market Economy Countries (April 5, 2005) (''Separate Rates and Combination Rates Bulletin''), available on the Department's Web site at *http://trade.gov/ia/policy/bull05-1.pdf.*

[40] *See* Separate Rates and Combination Rates Bulletin at 6 (emphasis added).

Distribution of Copies of the Petitions

In accordance with section 732(b)(3)(A) of the Act and 19 CFR 351.202(f), copies of the public version of the Petitions have been provided to the Governments of Malaysia, Thailand, and Vietnam via IA ACCESS. To the extent practicable, we will attempt to provide a copy of the public version of the Petitions to each exporter named in the Petitions, as provided under 19 CFR 351.203(c)(2).

ITC Notification

We have notified the ITC of our initiation, as required by section 732(d) of the Act.

Preliminary Determinations by the ITC

The ITC will preliminarily determine no later than July 1, 2013, whether there is a reasonable indication that imports of welded stainless pipe from Malaysia, Thailand, and Vietnam are materially injuring or threatening material injury to a U.S. industry. A negative ITC determination for any country will result in the investigation being terminated with respect to that country; otherwise, these investigations will proceed according to statutory and regulatory time limits.

Submission of Factual Information

On April 10, 2013, the Department published *Definition of Factual Information and Time Limits for Submission of Factual Information: Final Rule,* 78 FR 21246 (April 10, 2013), which modified two regulations related to AD and countervailing duty (CVD) proceedings: the definition of factual information (19 CFR 351.102(b)(21)), and the time limits for the submission of factual information (19 CFR 351.301). The final rule identifies five categories of factual information in 19 CFR 351.102(b)(21), which are summarized as follows: (i) Evidence submitted in response to questionnaires; (ii) evidence submitted in support of allegations; (iii) publicly available information to value factors under 19 CFR 351.408(c) or to measure the adequacy of remuneration under 19 CFR 351.511(a)(2); (iv) evidence placed on the record by the Department; and (v) evidence other than factual information described in (i)–(iv). The final rule requires any party, when submitting factual information, to specify under which subsection of 19 CFR 351.102(b)(21) the information is being submitted and, if the information is submitted to rebut, clarify, or correct factual information already on the record, to provide an explanation identifying the information already on the record that the factual information seeks to rebut, clarify, or correct. The final rule also modified 19 CFR 351.301 so that, rather than providing general time limits, there are specific time limits based on the type of factual information being submitted. These modifications are effective for all proceeding segments initiated on or after May 10, 2013, and thus are applicable to these investigations. Please review the final rule, available at *http://ia.ita.doc.gov/frn/2013/1304frn/2013-08227.txt*, prior to submitting factual information in these investigations.

Notification to Interested Parties

Interested parties must submit applications for disclosure under administrative protective order in accordance with 19 CFR 351.305. On January 22, 2008, the Department published *Antidumping and Countervailing Duty Proceedings: Documents Submission Procedures; APO Procedures,* 73 FR 3634 (Jan. 22, 2008). Parties wishing to participate in these investigations should ensure that they meet the requirements of these procedures (*e.g.,* the filing of letters of appearance as discussed at 19 CFR 351.103(d)).

Any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information.[41] Parties are hereby reminded that revised certification requirements are in effect for company/government officials as well as their representatives in all segments of any AD/CVD proceedings initiated on or after March 14, 2011.[42] The formats for the revised certifications are provided at the end of the *Interim Final Rule.* The Department intends to reject factual submissions in any proceeding segments if the submitting party does not comply with the revised certification requirements.

This notice is issued and published pursuant to section 777(i) of the Act.

Dated: June 5, 2013.

Paul Piquado,

for Import Administration.

Appendix I

Scope of the Investigations

The merchandise covered by these investigations is circular welded austenitic stainless pressure pipe not greater than 14 inches in outside diameter. For purposes of these investigations, references to size are in nominal inches and include all products within tolerances allowed by pipe specifications. This merchandise includes, but is not limited to, the American Society for Testing and Materials (ASTM) A–312 or ASTM A–778 specifications, or comparable domestic or foreign specifications. ASTM A–358 products are only included when they are produced to meet ASTM A–312 or ASTM A–778 specifications, or comparable domestic or foreign specifications.

Excluded from the scope are: (1) Welded stainless mechanical tubing, meeting ASTM A–554 or comparable domestic or foreign specifications; (2) boiler, heat exchanger, superheater, refining furnace, feedwater heater, and condenser tubing, meeting ASTM A–249, ASTM A–688 or comparable domestic or foreign specifications; and (3) specialized tubing, meeting ASTM A269, ASTM A–270 or comparable domestic or foreign specifications.

The subject imports are normally classified in subheadings 7306.40.5005, 7306.40.5040, 7306.40.5062, 7306.40.5064, and 7306.40.5085 of the Harmonized Tariff Schedule of the United States (HTSUS). They may also enter under HTSUS subheadings 7306.40.1010, 7306.40.1015, 7306.40.5042, 7306.40.5044, 7306.40.5080, and 7306.40.5090. The HTSUS subheadings are provided for convenience and customs purposes only; the written description of the scope of these investigations is dispositive.

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[41] *See* section 782(b) of the Act.

[42] *See Certification of Factual Information to Import Administration During Antidumping and Countervailing Duty Proceedings: Interim Final Rule,* 76 FR 7491 (February 10, 2011) (*Interim Final Rule*) amending 19 CFR 351.303(g)(1) & (2) and supplemented by *Certification of Factual Information To Import Administration During Antidumping and Countervailing Duty Proceedings: Supplemental Interim Final Rule,* 76 FR 54697 (September 2, 2011).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–823–810]

Solid Agricultural Grade Ammonium Nitrate from Ukraine: Continuation of Antidumping Duty Order

AGENCY: Import Administration, International Trade Administration, Department of Commerce.

SUMMARY: As a result of the determination by the Department of Commerce (''Department'') that revocation of the antidumping duty order [1] on solid agricultural grade ammonium nitrate from Ukraine would likely lead to continuation or recurrence of dumping, and the determination by the International Trade Commission (''ITC'') that revocation of the Order would likely lead to continuation or recurrence of material injury to an industry in the United States, the Department is publishing this notice of the continuation of the Order.

DATES: *Effective Date:* June 12, 2013.

[1] *See Antidumping Duty Order: Solid Agricultural Grade Ammonium Nitrate from Ukraine,* 66 FR 47451 (September 12, 2001) (''the Order'').

FOR FURTHER INFORMATION CONTACT: Mahnaz Khan, AD/CVD Operations, Office 1, Import Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482–0914.

SUPPLEMENTARY INFORMATION:

Background

On June 1, 2012, the Department and the ITC initiated the second sunset review of the Order on solid agricultural grade ammonium nitrate from Ukraine, pursuant to section 751(c) of the Tariff Act of 1930, as amended (''the Act'').[2] As a result of this sunset review, the Department determined that revocation of the Order on solid agricultural grade ammonium nitrate from Ukraine would be likely to lead to continuation or recurrence of dumping and notified the ITC of the magnitude of the margin likely to prevail should the order be revoked.[3]

On May 24, 2013, pursuant to section 752(a) of the Act, the ITC published its determination that revocation of the Order on solid agricultural grade ammonium nitrate from Ukraine would likely lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[4]

Scope of the Order

The merchandise covered by the order are solid, fertilizer grade ammonium nitrate (''ammonium nitrate'' or ''subject merchandise'') products, whether prilled, granular or in other solid form, with or without additives or coating, and with a bulk density equal to or greater than 53 pounds per cubic foot. Specifically excluded from the scope is solid ammonium nitrate with a bulk density less than 53 pounds per cubic foot (commonly referred to as industrial or explosive grade ammonium nitrate). The merchandise subject to the order is classified in the Harmonized Tariff Schedule of the United States (''HTSUS'') at subheading 3102.30.00.00. HTSUS subheadings are provided for convenience and customs purposes. The written description of the scope of the order is dispositive.

[2] *See Initiation of Five-Year (''Sunset'') Review,* 77 FR 32527 (June 1, 2012); and *Ammonium Nitrate from Ukraine: Institution of a Five-Year Review, Investigation No. 731–TA–894 (Second Review),* 77 FR 32669 (June 1, 2012).

[3] *See Solid Agricultural Grade Ammonium Nitrate from Ukraine: Final Results of the Expedited Second Sunset Review of the Antidumping Duty Order,* 77 FR 59377 (September 27, 2012).

[4] *See Certain Ammonium Nitrate from Ukraine,* 78 FR 32690 (May 31, 2013).

Continuation of the Order

As a result of the determinations by the Department and the ITC that revocation of this Order would likely lead to continuation or recurrence of dumping and material injury to an industry in the United States, pursuant to section 751(d)(2) of the Act, the Department hereby orders the continuation of the Order on solid agricultural grade ammonium nitrate from Ukraine.

U.S. Customs and Border Protection will continue to collect antidumping duty cash deposits at the rates in effect at the time of entry for all imports of subject merchandise. The effective date of continuation of these orders will be the date of publication in the **Federal Register** of this notice of continuation. Pursuant to section 751(c)(2) of the Act, the Department intends to initiate the next five-year review of this order not later than 30 days prior to the fifth anniversary of the effective date of continuation.

This five-year sunset review and this notice are in accordance with section 751(c) of the Act and published pursuant to section 777(i)(1) of the Act.

Dated: June 5, 2013.

Paul Piquado,

Assistant Secretary for Import Administration.

[FR Doc. 2013–13966 Filed 6–11–13; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

National Climate Assessment and Development Advisory Committee (NCADAC)

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of Open Meeting.

SUMMARY: The National Climate Assessment and Development Advisory Committee (NCADAC) was established by the Secretary of Commerce under the authority of the Global Change Research Act of 1990 to synthesize and summarize the science and information pertaining to current and future impacts of climate.

Time And Date: The meeting will be held July 9, 2013 from 1:00 p.m. to 6:00 p.m. EDT and July 10, 2013 from 9:00 a.m. to 4:30 p.m. These times are subject to change. Please refer to the Web page *http://www.globalchange.gov/* for changes and for the most up-to-date meeting agenda.

Location: The meeting will be held at NASA Headquarters, Room 2E39, 300 E Street SW., Washington, DC 20546. Please check the Web site *http://www.globalchange.gov/for* confirmation of the venue and for directions.

Status: Seating will be available on a first come, first serve basis. Members of the public must RSVP in order to attend all or a portion of the meeting by contacting the NCADAC DFO (*Cynthia.Decker@noaa.gov*) by Monday, July 1, 2013. The meeting will be open to public participation with a 15 minute public comment period on Tuesday, July 9, 2013 at 3:30 p.m. (check Web site to confirm time). The NCADAC expects that public statements presented at its meetings will not be repetitive of previously submitted verbal or written statements. In general, each individual or group making a verbal presentation will be limited to a total time of five (5) minutes. Individuals or groups planning to make a verbal presentation should contact the NCADAC DFO (*Cynthia.Decker@noaa.gov*) by Monday, July 1, 2013 to schedule their presentation. Written comments should be received in the NCADAC DFO's Office by Monday, July 1, 2013 to provide sufficient time for NCADAC review. Written comments received by the NCADAC DFO after Monday, July 1, 2013 will be distributed to the NCADAC, but may not be reviewed prior to the meeting date.

Special Accommodations: These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Dr. Cynthia Decker (301–563–6162, *Cynthia.decker@noaa.gov*) by Monday, July 1, 2013.

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Designated Federal Officer, National Climate Assessment and Development Advisory Committee, NOAA OAR, R/SAB, 1315 East-West Highway, Silver Spring, Maryland 20910. (Phone: 301–734–1156, Fax: 301–713–1459, Email: *Cynthia.Decker@noaa.gov;* or visit the NCADAC Web site at *http://www.globalchange.gov/.*

Dated: June 6, 2013.

Jason Donaldson,

Chief Financial Officer/Chief Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2013–13943 Filed 6–11–13; 8:45 am]

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DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Commerce Spectrum Management Advisory Committee Meeting

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of Open Meeting.

SUMMARY: This notice announces a public meeting of the Commerce Spectrum Management Advisory Committee (Committee). The Committee provides advice to the Assistant Secretary of Commerce for Communications and Information on spectrum management policy matters.

DATES: The meeting will be held on July 24, 2013, from 1:00 p.m. to 4:00 p.m., Eastern Daylight Time.

ADDRESSES: The meeting will be held at the U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4830, Washington, DC 20230. Public comments may be mailed to Commerce Spectrum Management Advisory Committee, National Telecommunications and Information Administration, 1401 Constitution Avenue NW., Room 4099, Washington, DC 20230 or emailed to *spectrumadvisory@ntia.doc.gov.*

FOR FURTHER INFORMATION CONTACT: Bruce M. Washington, Designated Federal Officer, at (202) 482–6415 or *BWashington@ntia.doc.gov;* and/or visit NTIA's Web site at *http://www.ntia.doc.gov/category/csmac.*

SUPPLEMENTARY INFORMATION:

Background: The Committee provides advice to the Assistant Secretary of Commerce for Communications and Information on needed reforms to domestic spectrum policies and management in order to: license radio frequencies in a way that maximizes their public benefits; keep wireless networks as open to innovation as possible; and make wireless services available to all Americans. *See* charter, at *http://www.ntia.doc.gov/other-publication/2013/csmac-2013-charter.* This Committee is subject to the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2, and is consistent with the National Telecommunications and Information Administration Act, 47 U.S.C. 904(b). The Committee functions solely as an advisory body in compliance with the FACA. For more information about the Committee visit: *http://www.ntia.doc.gov/category/csmac.*

Matters to Be Considered: The Committee will receive recommendations from its members on matters related to the accomplishment of the President's goal of identifying 500 megahertz of radio spectrum for wireless broadband by 2020. In addition, the Committee will report out on the recommendations from the following working groups (WGs) established to facilitate collaboration between industry and government stakeholders to develop proposed relocation, transition, and sharing arrangements and plans for the 1755–1850 MHz band:

1. WG3 1755–1850 MHz Satellite Control Links and Electronic Warfare,
2. WG4 1755–1850 MHz Fixed Point-to-Point and Tactical Radio Relay, and
3. WG5 1755–1850 MHz Airborne Operations.

NTIA will post a detailed agenda on its Web site, *http://www.ntia.doc.gov/category/csmac,* prior to the meeting. To the extent that the meeting time and agenda permit, any member of the public may speak to or otherwise address the Committee regarding the agenda items. During the portion of the meeting when the public may make an oral presentation, speakers may address only matters related to the agenda. See *Open Meeting and Public Participation Policy,* available at *http://www.ntia.doc.gov/category/csmac.*

Time and Date: The meeting will be held on July 24, 2013 from 1:00 p.m. to 4:00 p.m., Eastern Daylight Time. The times and the agenda topics are subject to change. The meeting will be available via two-way audio link and may be webcast. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/category/csmac,* for the most up-to-date meeting agenda and access information.

Place: The meeting will be held at the U.S. Department of Commerce, National Telecommunications and Information Administration, 1401 Constitution Avenue NW., Room 4830, Washington, DC 20230. The meeting will be open to the public and press on a first-come, first-served basis. Space is limited. The public meeting is physically accessible to people with disabilities. Individuals requiring accommodations, such as sign language interpretation or other ancillary aids, are asked to notify Mr. Washington, at (202) 482–6415 or *BWashington@ntia.doc.gov,* at least five (5) business days before the meeting.

Status: Interested parties are invited to attend and to submit written comments to the Committee at any time before or after the meeting. Parties wishing to submit written comments for consideration by the Committee in advance of a meeting must send them to NTIA's Washington, DC office at the above-listed address and comments must be received five (5) business days before the scheduled meeting date, to provide sufficient time for review. Comments received after this suspense date will be distributed to the Committee, but may not be reviewed prior to the meeting. It would be helpful if paper submissions also include a compact disc (CD) in Word or PDF format. CDs should be labeled with the name and organizational affiliation of the filer. Alternatively, comments may be submitted electronically to *spectrumadvisory@ntia.doc.gov.* Comments provided via electronic mail also may be submitted in one or more of the formats specified above.

Records: NTIA maintains records of all Committee proceedings. Committee records are available for public inspection at NTIA's Washington, DC office at the address above. Documents including the Committee's charter, member list, agendas, minutes, and any reports are available on NTIA's Committee Web page at *http://www.ntia.doc.gov/category/csmac.*

Dated: June 6, 2013.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2013–13840 Filed 6–11–13; 8:45 am]

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DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Multistakeholder Meeting To Develop Consumer Data Privacy Code of Conduct Concerning Mobile Application Transparency

AGENCY: National Telecommunications and Information Administration, U.S. Department of Commerce.

ACTION: Notice of Open Meeting.

SUMMARY: The National Telecommunications and Information Administration (NTIA) will convene a meeting of a privacy multistakeholder process concerning mobile application transparency. This Notice announces the meeting to be held on July 9, 2013.

DATES: The meeting will be held on July 9, 2013 from 1:00 p.m. to 5:00 p.m., Eastern Daylight Time. See **SUPPLEMENTARY INFORMATION** for details.

ADDRESSES: The meeting will be held in the Boardroom at the American Institute of Architects, 1735 New York Avenue NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: John Verdi, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401

Constitution Avenue NW., Room 4725, Washington, DC 20230; telephone (202) 482–8238; email *jverdi@ntia.doc.gov.* Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002.

SUPPLEMENTARY INFORMATION:

Background: On February 23, 2012, the White House released *Consumer Data Privacy in a Networked World: A Framework for Protecting Privacy and Promoting Innovation in the Global Digital Economy* (the ''Privacy Blueprint'').[1] The Privacy Blueprint directs NTIA to convene multistakeholder processes to develop legally enforceable codes of conduct that specify how the Consumer Privacy Bill of Rights applies in specific business contexts.[2] On June 15, 2012, NTIA announced that the goal of the first multistakeholder process is to develop a code of conduct to provide transparency in how companies providing applications and interactive services for mobile devices handle personal data.[3] On July 12, 2012, NTIA convened the first meeting of the first privacy multistakeholder process, followed by additional meetings through June 2013.

Matters to Be Considered: The July 9, 2013 meeting is part of a series of NTIA-convened multistakeholder discussions concerning mobile application transparency. Stakeholders will engage in an open, transparent, consensus-driven process to develop a code of conduct regarding mobile application transparency. The July 9, 2013 meeting will build on stakeholders' previous work. More information about stakeholders' work is available at: *http://www.ntia.doc.gov/other-publication/2012/privacy-multistakeholder-process-mobile-application-transparency.*

Time and Date: NTIA will convene a meeting of the privacy multistakeholder process on July 9, 2013 from 1:00 p.m. to 5:00 p.m., Eastern Daylight Time. The meeting time is subject to change. The meeting is subject to cancellation if stakeholders complete their work developing a code of conduct prior to the meeting date. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2012/privacy-multistakeholder-process-mobile-application-transparency,* for the most current information.

Place: The meeting will be held in the Boardroom at the American Institute of Architects, 1735 New York Avenue NW., Washington, DC 20006. The location of the meeting is subject to change. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2012/privacy-multistakeholder-process-mobile-application-transparency,* for the most current information.

Other Information: The meeting is open to the public and the press. The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to John Verdi at (202) 482–8238 or *jverdi@ntia.doc.gov* at least seven (7) business days prior to the meeting. The meeting will also be webcast. Requests for real-time captioning of the webcast or other auxiliary aids should be directed to John Verdi at (202) 482–8238 or *jverdi@ntia.doc.gov* at least seven (7) business days prior to the meeting. There will be an opportunity for stakeholders viewing the webcast to participate remotely in the meeting through a moderated conference bridge, including polling functionality. Access details for the meeting are subject to change. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2012/privacy-multistakeholder-process-mobile-application-transparency,* for the most current information.

Dated: June 6, 2013.

Kathy Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2013–13843 Filed 6–11–13; 8:45 am]

BILLING CODE 3510–60–P

[1] The Privacy Blueprint is available at *http://www.whitehouse.gov/sites/default/files/privacy-final.pdf.*

[2] *Id.*

[3] NTIA, *First Privacy Multistakeholder Meeting: July 12, 2012, http://www.ntia.doc.gov/other-publication/2012/first-privacy-multistakeholder-meeting-july-12-2012.*

COMMODITY FUTURES TRADING COMMISSION

Agency Information Collection Activities; Notice of Intent To Renew Collection: Market Surveys

AGENCY: Commodity Futures Trading Commission

ACTION: Notice.

SUMMARY: The Commodity Futures Trading Commission has submitted information collection 3038–0017, Market Surveys, to OMB for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The information collected pursuant to these rules is in the public interest and is necessary for market surveillance.

DATES: Comments must be received on or before July 12, 2013.

ADDRESSES: Persons wishing to comment on this information collection regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, should send comments to the addresses below. Please refer to OMB Control No. 3038–0017 in any correspondence.

Comments may be sent to Gary J. Martinaitis, Division of Market Oversight, U.S. Commodity Futures Trading Commission, 1155 21st Street NW., Washington, DC 20581; (202) 418; Fax (202) 418–5527; or Email: *gmartinaitis@cftc.gov.* and Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for CFTC, 725 17th Street NW., Washington, DC 20503.

Comments may also be submitted by any of the following methods: The agency's Web site, at *http://comments.cftc.gov.* Follow the instructions for submitting comments through the Web site.

Mail: Melissa D. Jurgens, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.

Hand Delivery/Courier: Same as mail above.

Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.

Please submit your comments using only one method and identify that it is for the renewal of collection 3038–0017.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to *www.cftc.gov.* You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.[1]

FOR FURTHER INFORMATION CONTACT: Gary J. Martinaitis, (202) 418–5209; FAX: (202) 418–5527; email: *gmartinaitis@cftc.gov.*

SUPPLEMENTARY INFORMATION: An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the CFTC's regulations were published on December 30, 1981. See 46 FR 63035 (Dec. 30, 1981). The **Federal Register**

[1] *See* 17 CFR 145.9.

notice with a 60-day comment period soliciting comments on this collection of information was published on April 8, 2013 (78 FR 20898).

Title: Market Surveys (OMB Control No. 3038–0017). This is a request for extension of a currently approved information collection.

Respondents: Businesses (excluding small businesses).

Estimated Annual Burden: 700 total hours.

Respondents	Businesses
Regulation (17 CFR)	21.02
Estimated number of respondents	400
Reports annually be each respondents	1
Total annual responses	400
Estimated number of hours per response	1.75

Dated: June 6, 2013.

Melissa D. Jurgens,

Secretary to the Commission.

[FR Doc. 2013–13878 Filed 6–11–13; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2013–OS–0132]

Proposed Collection; Comment Request

AGENCY: Defense Logistics Agency (DLA), DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Defense Logistics Agency (DLA) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by August 12, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at *http://www.regulations.gov* for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Logistics Agency, Security and Emergency Services Suite 3533, ATTN: Mr. Gregory Govan, Fort Belvoir, VA 22060 or call Security and Emergency Services at 703–767–5400.

Title; Associated Form; and OMB Number: Physical Access Control System; DLA Form 1815—Request for DLA Badge; OMB Control Number 0704–TBD.

Needs and Uses: The information collection requirement is needed to obtain the necessary data to verify eligibility for a Department of Defense physical access card for personnel who are not entitled to a Common Access Card or other approved DoD identification card. The information is used to establish eligibility for the physical access to a DLA installation or facility, detect fraudulent identification cards, provide physical access and population demographics reports, provide law enforcement data, and in some cases provide antiterrorism screening.

Affected Public: Individuals and households [Non-federal government employees and non-DoD credentialed individuals requesting access to any DLA Installation and/or facility.].

Annual Burden Hours: 25,000.

Number of Respondents: 100,000.

Responses per Respondent: 1.

Average Burden per Response: 15 minutes.

Frequency: On occasion.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Security Professionals (security administrators, security assistants, and/or Police officers) process the information to ensure personnel requesting and/or requiring access are properly identity proofed and vetted prior to allowing personnel access to any of the DLA installations and/or facilities. Respondents are individuals who require physical access to a DLA installation or facility. Basic identifying information is collected from the individuals, consisting of biographical data. Additional information may also be collected (such as contact information, vehicle information, organization affiliation, etc.) but may not be required for that individual to be registered and gain access to the DLA installation or facility.

Dated: June 4, 2013.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2013–13939 Filed 6–11–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Defense Acquisition Regulations System

[DFARS Case 2012–D055]

Detection and Avoidance of Counterfeit Electronic Parts

AGENCY: Defense Acquisition Regulations System, Department of Defense (DoD).

ACTION: Notice of meeting.

SUMMARY: DoD is hosting a public meeting to obtain the views of experts and interested parties in Government and the private sector regarding the electronic parts detection and avoidance coverage proposed to be included in the Defense Federal Acquisition Regulation Supplement.

DATES: June 28, 2013, from 9:00 a.m. to 12:30 p.m., EDT.

ADDRESSES: The public meeting will be held at General Services Administration (GSA), Central Office Auditorium, 1800 F Street NW., Washington, DC, 20405. The GSA auditorium is located on the main floor of the building.

FOR FURTHER INFORMATION CONTACT: Ms. Meredith Murphy, DPAP/DARS, at 571–

372–6098. Please cite DFARS Case 2012–D055 Public Meeting.

SUPPLEMENTARY INFORMATION: DoD is interested in opening a dialogue with experts and interested parties in Government and the private sector about the requirements for detection and avoidance of counterfeit electronic parts in DoD contracts. A proposed rule was published in the **Federal Register** at 78 FR 28780 on May 16, 2013. The public comment period closes on July 15, 2013.

The DFARS proposed rule is a partial implementation of the requirements at section 818, entitled ''Detection and Avoidance of Counterfeit Electronic Parts,'' of the National Defense Authorization Act for Fiscal Year 2012 (Pub. L. 112–81).

The DFARS case would apply only to contractors subject to the Cost Accounting Standards. It addresses the responsibility of DoD contractors for detecting and avoiding the use or inclusion of counterfeit electronic parts or suspect counterfeit electronic parts in items delivered to the Department. In lieu of requiring contractors to establish an entirely new and separate system for avoiding the purchase, and detecting the receipt, of counterfeit or suspect counterfeit parts, DoD plans to use contractors' existing purchasing systems and quality assurance systems.

In addition, the DFARS case proposes to implement section 833, entitled ''Contractor Responsibilities in Regulations Relating to Detection and Avoidance of Counterfeit Electronic Parts,'' of the National Defense Authorization Act for Fiscal Year 2013 (Pub. L. 112–239). This provision of law makes the costs associated with counterfeit or suspect counterfeit parts unallowable except in certain limited circumstances.

Individuals wishing to attend the public meeting should register by June 20, 2013, to ensure adequate room accommodations and to facilitate entry to the GSA building. Interested parties may register at this Web site, *http://www.acq.osd.mil/dpap/dars/counterfeit_electronic_parts.html,* by providing the following information:

- (1) Company or organization name;
- (2) Names and email addresses of persons planning to attend;
- Identify if desiring to make a presentation; limit to a 10-minute presentation per company or organization.
- Last four digits of the social security number for anyone who is not a Federal Government employee with a Government badge, in order to create an attendee list for secure entry to the GSA building.

Attendees are encouraged to arrive at least 30 minutes early to accommodate security procedures.

If you wish to make a presentation, please submit an electronic copy of your presentation to *dfars@osd.mil* no later than June 24, 2013. When submitting presentations, provide presenter's name, organization affiliation, telephone number, and email address on the cover page. Please submit presentations only and cite DFARS Case 2012–D055 Public Meeting in all correspondence related to the public meeting. There will be no transcription at the meeting. The submitted presentations will be the only record of the public meeting.

Special accommodations: The public meeting is physically accessible to people with disabilities. Requests for reasonable accommodations, sign language interpretation or other auxiliary aids should be directed to Meredith Murphy at 571–372–6098, at least 10 working days prior to the meeting date.

The TTY number for further information is: 1–800–877–8339. When the operator answers the call, let them know the agency is the Department of Defense; the point of contact is Meredith Murphy at 571–372–6098.

Kortnee Stewart,

Editor, Defense Acquisition Regulations System.

[FR Doc. 2013–13960 Filed 6–11–13; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF ENERGY

[FE Docket No. 13–51–LNG]

Freeport LNG Development, L.P.; Application for Blanket Authorization To Export Previously Imported Liquefied Natural Gas on a Short-Term Basis

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of an application (Application), filed on April 19, 2013, by Freeport LNG Development, L.P. (Freeport LNG), requesting blanket authorization to export liquefied natural gas (LNG) that previously had been imported into the United States from foreign sources in a cumulative amount up to the equivalent of 24 billion cubic feet (Bcf) of natural gas on a short-term or spot market basis for a two-year period commencing on July 19, 2013.[1] The LNG would be exported from the existing Freeport LNG Terminal facilities on Quintana Island, Texas, to any country with the capacity to import LNG via ocean-going carrier and with which trade is not prohibited by U.S. law or policy. Freeport LNG is requesting authorization both to export LNG to which it holds title on its own behalf and as agent for parties who hold title to the LNG at the time of export. The Application was filed under section 3 of the Natural Gas Act (NGA). Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., eastern time, July 12, 2013.

ADDRESSES: *Electronic Filing by email: fergas@hq.doe.gov*

Regular Mail

U.S. Department of Energy (FE–34), Office of Oil and Gas Global Security and Supply, Office of Fossil Energy, P.O. Box 44375, Washington, DC 20026–4375.

Hand Delivery or Private Delivery Services (e.g., FedEx, UPS, etc.)

U.S. Department of Energy (FE–34), Office of Oil and Gas Global Security and Supply, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Larine Moore or Beverly Howard, U.S. Department of Energy (FE–34), Office of Oil and Gas Global Security and Supply, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9478; (202) 586–9387.

Edward Myers, U.S. Department of Energy, Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, Room 6B–256, 1000 Independence Ave. SW., Washington, DC 20585, (202) 586–3397.

SUPPLEMENTARY INFORMATION:

Background

Freeport LNG is a Delaware limited partnership with four limited partners: (1) Freeport LNG Investments, LLP, a Delaware limited liability limited partnership, which owns a 20% limited partnership interest in Freeport LNG; (2) ZHA FLNG Purchaser LLC, a Delaware limited liability company, which owns

[1] *Freeport LNG Development, L.P.,* DOE/FE Order No. 2986 (July 19, 2011) extends through July 18, 2013 (FE Docket No. 11–51–LNG).

a 55% limited partnership interest in Freeport LNG; (3) Texas LNG Holdings, LLC, a Delaware limited liability company and wholly-owned subsidiary of The Dow Chemical Company, which owns a 15% limited partnership interest in Freeport LNG; and (4) Turbo LNG, LLC, a Delaware limited liability company and wholly-owned subsidiary of Osaka Gas Co., Ltd., which owns a 10% limited partnership interest in Freeport LNG. In addition to the limited partners, Freeport LNG has one general partner that manages the company, Freeport LNG–GP, Inc., a Delaware corporation, which is owned 50% by MS GP Holdco, LLC, an entity owned by an individual, Michael S. Smith, and 50% by ConocoPhillips Company. Freeport LNG has its principal place of business in Houston, Texas.

On June 18, 2004, the Federal Energy Regulatory Commission (FERC) authorized Freeport LNG to site, construct and operate the Freeport LNG Terminal on Quintana Island, southeast of the City of Freeport in Brazoria County, Texas. The facilities, completed in June 2008, include an LNG ship marine terminal and unloading dock, LNG transfer lines and storage tanks, high-pressure vaporizers, and a 9.6-mile long send-out pipeline extending to the Stratton Ridge meter station.[2] On July 1, 2008, FERC issued a letter Order granting Freeport LNG's request to commence service at its Quintana Island import terminal.

On May 28, 2009, in DOE/FE Order No. 2644, DOE/FE granted Freeport LNG authorization to export previously imported foreign-sourced LNG, on its own behalf or as an agent for others, up to a cumulative total equivalent to 24 Bcf of natural gas from the Freeport LNG Terminal to certain countries in Europe and Asia for a two-year period that extended through May 27, 2011. In amendments set forth in DOE/FE Order Nos. 2644–A and 2644–B, Freeport LNG was authorized to export this LNG to any country not prohibited by U.S. law that has capacity to import LNG via ocean-going carrier.

On July 19, 2011, in DOE/FE Order No. 2986, DOE/FE extended this authorization for an additional two years. Specifically, DOE/FE granted Freeport LNG blanket authorization to export previously imported foreign-sourced LNG, on its own behalf or as agent for others, up to a cumulative total equivalent to 24 Bcf of natural gas from the Freeport LNG Terminal for an additional two-year period that extends through July 18, 2013, to any country with the capacity to import LNG via ocean-going carrier and with which trade was not prohibited by U.S. law or policy.

Current Application

The current Application is filed in anticipation of the upcoming expiration of Order No. 2986 on July 18, 2013, and requests the same type of authorization previously granted in that Order. Freeport LNG therefore requests this blanket authorization to export previously imported foreign-sourced LNG, on its own behalf or as agent for others who hold title to the LNG at the time of export, up to a cumulative total equivalent to 24 Bcf of natural gas from the Freeport LNG Terminal for a two-year period, beginning on July 19, 2013. Freeport LNG is seeking such authorization to export previously imported LNG to any country with the capacity to import LNG via ocean-going carrier and with which trade is not prohibited by Federal law or policy. Freeport LNG states that it does not seek authorization to export domestically-produced natural gas or LNG.

Public Interest Considerations

Freeport LNG asserts that the proposed authorization is in the public interest. In support of its Application, Freeport LNG states that section 3 of the NGA provides that application to export natural gas to foreign countries will be authorized unless there is a finding that such exports ''will not be consistent with the public interest.''[3] Freeport LNG states that Section 3 thus creates a statutory presumption in favor of approval of this application, and that parties opposing the authorization bear the burden of overcoming this presumption.

Freeport LNG states that, in its existing authorization to export foreign-sourced LNG granted in Order 2986, DOE/FE determined that there was no domestic reliance on the volumes of imported LNG that Freeport LNG sought to export. As before, the imported LNG that Freeport LNG seeks to export will be surplus to the demands of U.S. markets during the period of requested authorization, and is needed primarily to enable Freeport LNG to economically maintain and operate its Quintana Island terminal. Freeport LNG asserts that, as there is no reliance on domestic supplies, the requested authorization is not inconsistent with the public interest. Freeport LNG further asserts that this proposed authorization meets the requirements of DOE Delegation Order No. 0204–111, which requires ''consideration of the domestic need for the gas to be exported.'' [4]

Freeport LNG states that the authorization requested will provide commercial flexibility to help ensure the full and continual operation of its LNG import facilities at the Quintana Island terminal. Freeport LNG further states that the proposed export of foreign-sourced LNG will not reduce local or domestic supplies of natural gas.

Freeport LNG emphasizes that the requested authorization will ensure the operational readiness of essential infrastructure at its Quintana Island terminal. Freeport LNG states that, if the continuous cryogenic operations of the terminal facility were interrupted, it would require several weeks to restore the system to operational readiness. Furthermore, if operations were interrupted, Freeport LNG and its Quintana Island terminal would be unable to respond to changes in U.S. natural gas market conditions should those occur. For these reasons, Freeport LNG asserts that ensuring the continuing operation of essential U.S. energy infrastructure is consistent with the public interest.

Environmental Impact

Freeport LNG states that no change to the Freeport LNG Terminal on Quintana Island would be required for the proposed export of foreign-sourced LNG. Thus, according to Freeport LNG, approval of this application will not constitute a federal action significantly affecting the human environment within the meaning of the National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* and no environmental impact statement or environmental assessment will be required.

DOE/FE Evaluation

The Application will be reviewed pursuant to section 3(a) of the NGA, 15 U.S.C. 717b(a), and the authority contained in DOE Delegation Order No. 00–002.00L (April 29, 2011) and DOE Redelegation Order No. 00–002.04E (April 29, 2011). In reviewing this Application, DOE will consider domestic need for the natural gas, as well as any other issues determined to be appropriate, including whether the arrangement is consistent with DOE's

[2] *See Freeport LNG Development, L.P.,* 107 FERC ¶ 61,278, (2004), *order granting rehearing and clarification,* 108 FERC ¶ 61,253 (2004), *order amending Section 3 authorization,* 112 FERC ¶ 61,194 (2005), *order issuing authorization,* 116 FERC ¶ 61,290 (2006).

[3] 15 U.S.C. 717b(a). Natural gas is defined to include LNG in 10 CFR 590.102(i).

[4] New Policy Guidelines and Delegations Order Relating to Regulation of Imported Natural Gas, 49 FR 6684 (Feb. 22, 1984).

policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. Persons that may oppose this Application should comment in their responses on these issues.

NEPA requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its NEPA responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention, as applicable. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590. The information contained in any filing will not be held confidential and will be posted to DOE's public Web site except to the extent confidential treatment is requested and granted.

Filings may be submitted using one of the following methods: (1) E-Mailing the filing to *fergas@hq.doe.gov,* with FE Docket No. 13–51–LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Oil and Gas Global Security and Supply at the address listed in **ADDRESSES**; or (3) hand delivering an original and three paper copies of the filing to the Office of Oil and Gas Global Security and Supply at the address listed in **ADDRESSES**. All filings must include a reference to FE Docket No. 13–51–LNG.

A decisional record on the Application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. A party seeking intervention may request that additional procedures be provided, such as additional written comments, an oral presentation, a conference, or trial-type hearing. Any request to file additional written comments should explain why they are necessary. Any request for an oral presentation should identify the substantial question of fact, law, or policy at issue, show that it is material and relevant to a decision in the proceeding, and demonstrate why an oral presentation is needed. Any request for a conference should demonstrate why the conference would materially advance the proceeding. Any request for a trial-type hearing must show that there are factual issues genuinely in dispute that are relevant and material to a decision and that a trial-type hearing is necessary for a full and true disclosure of the facts.

If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

The Application is available for inspection and copying in the Office of Oil and Gas Global Security and Supply docket room, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: *http://www.fe.doe.gov/programs/gasregulation/index.html.*

Issued in Washington, DC, on June 5, 2013.

John A. Anderson,

Manager, Natural Gas Regulatory Activities, Office of Oil and Gas Global Security and Supply, Office of Fossil Energy.

[FR Doc. 2013–13944 Filed 6–11–13; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Efficiency and Renewable Energy

State Energy Advisory Board (STEAB); Correction

AGENCY: Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of Open Meeting: Correction.

SUMMARY: The Department of Energy (DOE) published in the **Federal Register** on April 4, 2013, a notice of an open meeting for the State Energy Advisory Board (STEAB). The notice is being corrected to change the dates of the meeting.

Correction

In the **Federal Register** of April 4, 2013, in FR DOC. 2013–07832, on page 20311, please make the following corrections:

In the **DATES** heading, third column, first paragraph, first line, please remove, ''June 25, 2013'' and ''June 26, 2013'' and add in its place add ''July 17, 2013'' and ''July 18, 2013''.

In the **ADDRESSES** heading, third column, first paragraph, second line, please remove, ''(in the Jefferson Meeting Room)''.

Issued in Washington, DC on June 6, 2013.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2013–13958 Filed 6–11–13; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2010–0014; FRL–9388–6]

Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw its requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registration has been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before December 9, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2010–0014, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI)

or other information whose disclosure is restricted by statute.

• *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

Submit written withdrawal request by mail to: Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. ATTN: John W. Pates, Jr.

• *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: John W. Pates, Jr., Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8195; email address: *pates.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What action is the agency taking?

This notice announces receipt by the Agency of requests from registrants to cancel 54 pesticide products registered under FIFRA section 3 or 24(c). These registrations are listed in sequence by registration number (or company number and 24(c) number) in Table 1 of this unit.

Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue an order in the **Federal Register** canceling all of the affected registrations.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product name	Chemical name
000264–00668	Liberty ATZ Herbicide	Atrazine, Glufosinate.
000264–00784	Renounce 20WP Insecticide	Cyfluthrin.
000264–00985	GB34 Concentrate Biological Fungicide	Bacillus pumilus strain GB34.
000264–00986	GB34 Technical Biological Fungicide	Bacillus pumilus strain GB34.
000264–01007	Decis 0.2 EC	Deltamethrin.
000264–01008	Decis 0.2 EC Gel	Deltamethrin.
000264–01012	Decis 1.0 Gel Insecticide	Deltamethrin.
000264–01117	Yield Shield FS 200	Bacillus pumilus strain GB34.
000400–00469	Dimilin 25W Mushrooms	Diflubenzuron.
000400–00470	Dimilin 35W for Pasturegrass Mosquitoes	Diflubenzuron.
000400–00471	Micromite 25WS	Diflubenzuron.
000400–00511	Dimilin 80WGS	Diflubenzuron.
000432–00954	Finale Super Concentrate Weed, Grass and Brush Killer	Glufosinate.
000432–00955	Finale Ready-To-Use Weed and Grass Killer	Glufosinate.
000432–00956	Finale Concentrate Weed, Grass and Brush Killer	Glufosinate.
000655–00802	Prentox Larva-Lur Contains Propoxur	Propoxur.
009779–00262	MCPA Amine Herbicide	MCPA, dimethylamine salt.
009779–00265	MCPA LV Ester	MCPA, 2-ethylhexyl ester.
053883–00220	Oryzalin 2G	Oryzalin, Benfluralin.
AL–090001	Reflex Herbicide	Sodium salt of fomesafen.
AR–080004	Reflex Herbicide	Sodium salt of fomesafen.
AR–080005	Superwham! (Alternate Name Forwham ! EZ)	Propanil.
AR–080006	Riceshot	Propanil.
AR–080007	Ricepro	Quinclorac, Propanil.
AR–080008	Duet	Propanil, Bensulfuron-methyl.
AR–080009	Superwham! (Alternate Name For Wham! EZ)	Propanil.
AR–080013	Ricebeaux	Propanil, Thiobencarb.
AR–120001	Ricebeaux Herbicide	Thiobencarb, Propanil.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION—Continued

Registration No.	Product name	Chemical name
AR–120002	Ricebeaux	Thiobencarb, Propanil.
AR–120003	Ricepro	Quinclorac, Propanil.
CO–060007	Gramoxone Inteon	Paraquat dichloride.
FL–090006	Knockout	Diquat dibromide.
GA–090005	Milestone VM	Triisopropanolamine salt of aminopyralid.
GA–100004	Endigo ZC	Thiamethoxam lambda-Cyhalothrin.
MO–120006	V–10142 AG Herbicide	Imazosulfuron.
ND–020009	Bravo 720	Chlorothalonil.
OR–010006	Cobra Herbicide	Lactofen.
OR–040015	Ethrel Brand Ethephon Plant Regulator	Ethephon.
OR–040031	Rovral 4 Flowable Fungicide	Iprodione.
OR–050017	Simazine 4L	Simazine.
OR–070002	Chateau Herbicide WDG	Flumioxazin.
OR–070019	Acramite-4SC	Bifenazate.
OR–070022	RTU-Vitavax-Thiram Seed Protectant Fungicide	Thiram, Carboxin.
OR–070028	Define SC Herbicide	Flufenacet.
OR–070030	Define SC Herbicide	Flufenacet.
OR–080020	DuPont Direx 4L Herbicide	Diuron.
OR–100004	Chateau Herbicide WDG	Flumioxazin.
OR–120009	Palisade 2EC	Trinexapac-ethyl.
WA–000021	Orthene 97 Pellets	Acephate.
WA–010038	Crossbow	2,4–D butoxyethyl ester acetic acid (3,5,6-trichloro-2-pyridinyl) oxy)-,2-butoxyethel ester.
WA–020012	Echo 720	Chlorothalonil.
WA–060017	Orthene 97	Acephate.
WA–810064	Orthene 75 S Soluble Powder	Acephate.
WA–960024	Orthene 75 S Soluble Powder	Acephate.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in this unit.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company name and address
264:	
OR–040015; OR–040022; OR–040031; OR–070022; OR–070028; OR–070030.	Bayer CropScience, LP, 2 T.W. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709.
400:	
OR–070019	Chemtura Corporation, 199 Benson Rd., Middlebury, CT 06749.
432	Bayer Environmental Science, A Division of Bayer CropScience, LP, 2 T.W. Alexander Dr., P.O. Box 12014, Research Triangle Park, NC 27709.
655	Prentis, LLC, Agent: Pyxis Regulatory Consulting, Inc., 4110 136th St., NW., Gig Harbor, WA 98332.
9779:	
OR–080020	Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164–058.
53883	Control Solutions, Inc., 5903 Genoa Red Bluff, Pasadena, TX 77507–1041.
AL–090001; AR–080004; CO–060007; FL–090006; GA–100004; ND–020009; OR–120009.	Syngenta Crop Protection, LLC, 410 Swing Rd., P.O. Box 18300, Greensboro, NC 27419–8300.
AR–080005; AR–080006; AR–080007; AR–080008; AR–080009; AR–080013; AR–120001; AR–120002; AR–120003.	Riceco, LLC, 5100 Poplar Ave., Suite 2428, Memphis, TN 38137.
GA–090005; WA–010038	Dow AgroSciences, LLC, 9330 Zionsville Rd., 308/2E, Indianapolis, IN 46268–1054.
MO–120006; OR–100004; OR–010006; OR–070002.	Valent U.S.A. Corporation, 1600 Riviera Ave., Suite 200, Walnut Creek, CA 94596.
OR–050017	Loveland Products, P.O. Box 1286, Greeley, CO 80632–1286.
WA–000021; WA–060017; WA–810064; WA–960024.	Amvac Chemical Corporation, 4695 MacArthur Ct., Suite 1200, Newport Beach, CA 92660–1706.
WA–020012	Sipcam Agro U.S.A., Inc., 2520 Meridian Pkwy., Suite 525, Durham, NC 27713.

III. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary

cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants in Table 2 of Unit II., have not requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 180-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation should submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Because the Agency has identified no significant potential risk concerns associated with these pesticide products, upon cancellation of the products identified in Table 1 of Unit II., EPA anticipates allowing registrants to sell and distribute existing stocks of these products for 1 year after publication of the Cancellation Order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing the pesticides identified in Table 1 of Unit II., except for export consistent with FIFRA section 17 or for proper disposal. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 4, 2013.

Michael Goodis,

Acting, Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2013–13817 Filed 6–11–13; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2009–1017; FRL–9388–5]

Notice of Receipt of Requests To Voluntarily Cancel Certain Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In accordance with the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is issuing a notice of receipt of requests by registrants to voluntarily cancel certain pesticide registrations. EPA intends to grant these requests at the close of the comment period for this announcement unless the Agency receives substantive comments within the comment period that would merit its further review of the requests, or unless the registrants withdraw its requests. If these requests are granted, any sale, distribution, or use of products listed in this notice will be permitted after the registration has been cancelled only if such sale, distribution, or use is consistent with the terms as described in the final order.

DATES: Comments must be received on or before July 12, 2013.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPP–2009–1017, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

Submit written withdrawal request by mail to: Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001. ATTN: John W. Pates, Jr.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.htm.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: John W. Pates, Jr., Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 308–8195; email address: *pates.john@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides.

B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD–ROM that you mail to EPA, mark the outside of the disk or CD–ROM as CBI and then identify electronically within the disk or CD–ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at

your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. What action is the Agency taking?

This notice announces receipt by the Agency of requests from registrants to cancel 45 pesticide products registered under FIFRA section 3 or 24(c). These registrations are listed in sequence by registration number (or company number and 24(c) number) in Table 1. of this unit.

Unless the Agency determines that there are substantive comments that warrant further review of the requests or the registrants withdraw their requests, EPA intends to issue an order in the **Federal Register** canceling all of the affected registrations.

TABLE 1—REGISTRATIONS WITH PENDING REQUESTS FOR CANCELLATION

Registration No.	Product name	Chemical name
000100–01104	Tralkoxydim Technical	Tralkoxydim.
000100–01130	Achieve SC Herbicide	Tralkoxydim.
000192–00163	Dexol Rose & Floral Insect Killer	Piperonyl butoxide, Pyrethrins (no inert use).
000192–00198	Dexol Multipurpose Insect Spray	Permethrin.
000192–00222	Allpro Permeththrin ICG .5%	Permethrin.
000239–02709	Ortho MAT28S RTU	Aminocyclopyrachlor.
000239–02710	Ortho MAT28N RTU	Aminocyclopyrachlor.
000239–02711	Ortho MAT28NS Conc	Aminocyclopyrachlor.
000239–02712	Ortho MAT28N Combo	Aminocyclopyrachlor, Dicamba, Quinclorac.
000239–02713	Ortho MAT28N Combo Concentrate	Aminocyclopyrachlor, Dicamba, Quinclorac.
000264–01028	Mepiquat Chloride Technical Plant Regulator	Mepiquat chloride.
000499–00465	Pro-Control Fogger II	MGK 264, Pipernoyl butoxide, Pyrethins (no inert use).
000538–00319	Ortho MAT28N Combo Concentrate	Aminocyclopyrachlor.
000538–00320	Scotts 65 MAT Weed & Feed	Aminocyclopyrachlor.
000538–00321	Scotts 55 MAT Weed & Feed	Aminocyclopyrachlor.
000538–00322	Scotts 60 MAT Weed & Feed	Aminocyclopyrachlor.
000577–00541	Cuprinol Wood Preservative Green No. 10	Copper naphthenate.
001021–01060	D-trans Allethrin 90% Concentrate	d-trans-Chrysanthemum monocarboxylic ester of dl-2-allyl-4-hydoroxy-3-methyl-2-cylopenten-1-one.
001021–01128	D-trans Intermediate 1868	d-trans-Chrysanthemum monocarboxylic ester of dl-2-allyl-4-hydoroxy-3-methyl-2-cylopenten-1-one, MGK 264, Piperonyl butoxide.
001021–01550	Evercide Intermediate 2416	d-trans-Chrysanthemum monocarboxylic ester of dl-2-allyl-4-hydoroxy-3-methyl-2-cylopenten-1-one, MGK 264, Permethrin.
001021–01575	Evercide Intermediate 2491	d-trans-Chrysanthemum monocarboxylic ester of dl-2-allyl-4-hydoroxy-3-methyl-2-cylopenten-1-one, MGK 264 Piperonyl butoxide, Esfenvalerate.
001021–01594	Evercide Residual Pressurized Spray 2523	d-trans-Chrysanthemum monocarboxylic ester of dl-2-allyl-4-hydoroxy-3-methyl-2-cylopenten-1-one, MGK 264, Piperonyl butoxide, Esfenvalerate.
001021–01607	Evercide Residual Pressurized Spray 2581	d-trans-Chrysanthemum monocarboxylic ester of dl-2-allyl-4-hydoroxy-3-methyl-2-cylopenten-1-one, MGK 264, Permethrin.
005481–00130	Fruit Fix Concentrate 800	Ammonium 1-naphthaleneacetate.
005481–00459	Prune Smart Sprout Inhibitor	Ethyl 1-naphthaleneacetate.
005481–00496	Snaap-2	Potassium 1-naphthaleneacetate.
005481–00497	Snaap-8	Potassium 1-naphthaleneacetate.
009779–00298	Riverside Copper Hydroxide 77DF	Copper hydroxide.
010163–00293	GWN–3771 Technical Herbicide	Thifensulfuron.
010163–00294	GWN–3124 WDG Herbicide	Thifensulfuron.
010163–00299	GWN–3125 WDG Herbicide	Tribenuron-methyl.
010163–00300	GWN–3123 WDG Herbicide	Tribenuron-methyl, Thifensulfuron.
010807–00436	Konk Insect Killer	d-trans-Chrysanthemum monocarboxylic ester of dl-2-allyl-4-hydroxy-3-methyl-2-cyclopenten-1-one, MGK 264, Permethrin.
045385–00093	CTX/Cyber Blast	MGK 264, Prallethrin, Esfenvalerate.
053883–00128	Propiconazole HG	Propiconazole.
053883–00220	Oryzalin 2G	Oryzalin, Benfluralin.
055260–00007	BDL 1633 Industrial Microbiocide	Dodecylguanidine hydrochloride.
082397–00002	Chem-Fish Synergized	Piperonyl butoxide, Rotenone, Cube Resins other than rotenone.
082397–00003	Powdered Cube Root	Rotenone, Cube Resins other than rotenone.
086363–00014	KT Propicon 3.6EC	Propiconazole.
MN070006	Chem Sect Brand Chem Fish Synergized	Piperonyl butoxide, Rotenone, Cube Resins other than rotenone.
OR910030	K-Salt Fruit Fix 200	Potassium 1-naphthaleneacetate.
OR910031	K-Salt Fruit Fix 800	Potassium 1-naphthaleneacetate.
WA050004	Fruitone-N	Sodium 1-naphthaleneacetate.
WA910050	K-Salt Fruit Fix 200	Potassium 1-naphthaleneacetate.

Table 2. of this unit includes the names and addresses of record for all registrants of the products in Table 1. of this unit, in sequence by EPA company number. This number corresponds to the first part of the EPA registration numbers of the products listed in this unit.

TABLE 2—REGISTRANTS REQUESTING VOLUNTARY CANCELLATION

EPA Company No.	Company name and address
100	Syngenta Crop Protection, LLC, 410 Swing Road, P.O. Box 18300, Greensboro, NC 27419–8300.
192	Value Garden Supply, LLC, D/B/A Value Garden Supply, PO Box 585, Saint Joseph, MO 64502.
239	The Scotts Company, D/B/A The Ortho Group, PO Box 190, Marysville, OH 43040.
264	Bayer Cropscience LP, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709.
499	Whitmore Micro-Gen Research Laboratories, Inc. Agent: BASF Corporation, 3568 Tree Court Industrial Blvd., St. Louis, MO 63122–6682.
538	The Scotts Company, 14111 Scottslawn Road, Marysville, OH 43041.
577	Sherwin-Williams Co., 101 Prospect Ave., Cleveland, OH 44115–1075.
1021	McLaughlin Gormley King Co, D/B/A MGK, 8810 Tenth Ave North, Minneapolis, MN 55427–4319.
5481, OR910030, OR910031, WA050004, WA910050.	Amvac Chemical Corporation, 4695 MacArthur Court, Suite 1200, Newport Beach, CA 92660–1706.
9779	Winfield Solutions, LLC, P.O. Box 64589, St. Paul, MN 55164–0589.
10163	Gowan Company, PO Box 5569, Yuma, AZ 85366–8844.
10807	Amrep, Inc. 990 Industrial Park Drive Marietta, GA 30062.
45385	CTX-Cenol, Inc., 1393 East Highland Road, Twinsburg, OH 44087.
53883	Control Solutions, Inc., 5903 Genoa-Red Bluff Road, Pasadena, TX 77507–1041.
55260	Agriphar S.A., Agent: Ceres International LLC, 1087 Heartsease Drive, West Chester, PA 19382.
62190	Arch Wood Protection, Inc., 5660 New Northside Drive, N.W., Suite 1100, Atlanta, GA 30328.
82397, MN070006	Tifa International LLC, 109 Stryker Lane, Hillsborough, NJ 08844.
86363	Kaizen Technologies, LLC Agent: Lighthouse Product Services, 1966 W. 15th Street, Suite 6, Loveland, CO 80538.

III. What is the Agency's authority for taking this action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be canceled. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**.

Section 6(f)(1)(B) of FIFRA requires that before acting on a request for voluntary cancellation, EPA must provide a 30-day public comment period on the request for voluntary cancellation or use termination. In addition, FIFRA section 6(f)(1)(C) requires that EPA provide a 180-day comment period on a request for voluntary cancellation or termination of any minor agricultural use before granting the request, unless:

1. The registrants request a waiver of the comment period, or

2. The EPA Administrator determines that continued use of the pesticide would pose an unreasonable adverse effect on the environment.

The registrants in Table 2. of Unit II. have requested that EPA waive the 180-day comment period. Accordingly, EPA will provide a 30-day comment period on the proposed requests.

IV. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for cancellation should submit such withdrawal in writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. If the products have been subject to a previous cancellation action, the effective date of cancellation and all other provisions of any earlier cancellation action are controlling.

V. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products that are currently in the United States and that were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. Because the Agency has identified no significant potential risk concerns associated with these pesticide products, upon cancellation of the products identified in Table 1. of Unit II., EPA anticipates allowing registrants to sell and distribute existing stocks of these products (except for registration no. 000100–01104 and 000100–01130) for 1 year after publication of the cancellation order in the **Federal Register**. Thereafter, registrants will be prohibited from selling or distributing the pesticides identified in Table 1. of Unit II., except for export consistent with FIFRA section 17 or for proper disposal. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted, provided that such sale, distribution, or use is consistent with the terms of the previously approved labeling on, or that accompanied, the canceled products.

The continued sale and distribution of existing stocks of these products (registration no. 000100–01104 and 000100–01130) will be allowed through November 1, 2014. Additionally, the use of existing stocks of these products will be allowed until those existing stocks are exhausted.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 4, 2013.

Michael Goodis,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2013–13978 Filed 6–11–13; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within ten days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)–523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 010979–056.

Title: Caribbean Shipowners Association.

Parties: CMA CGM SA; Crowley Caribbean Services LLC; Hybur Ltd.; Seaboard Marine, Ltd.; Seafreight Line, Ltd.; Tropical Shipping and Construction Company Limited; King Ocean Services Limited; and Zim Integrated Shipping Services, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor, 1627 I Street, NW; Washington, DC 20006.

Synopsis: The amendment would add the Bahamas to the geographic scope of the agreement.

Agreement No.: 011223–049.

Title: Transpacific Stabilization Agreement.

Parties: American President Lines, Ltd. and APL Co. PTE Ltd. (operating as a single carrier); A.P. Moller-Maersk A/S trading under the name of Maersk Line; China Shipping Container Lines (Hong Kong) Company Limited and China Shipping Container Lines Company Limited (operating as a single carrier); CMA CGM S.A.; COSCO Container Lines Company, Ltd; Evergreen Line Joint Service Agreement, FMC No. 011982; Hanjin Shipping Co., Ltd.; Hapag-Lloyd A.G.; Hyundai Merchant Marine Co., Ltd.; Kawasaki Kisen Kaisha, Ltd.; Mediterranean Shipping Company S.A.; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; Yangming Marine Transport Corp.; and Zim Integrated Shipping Services, Ltd.

Filing Party: David F. Smith, Esq.; Cozen O'Connor; 6271 I Street, NW; Suite 1100; Washington, DC 20006.

Synopsis: The amendment deletes Siberia Russia from the geographic scope of the agreement.

Agreement No.: 012210.

Title: Siem Car Carrier Pacific AS/Eukor Car Carriers Inc. Space Charter Agreement.

Parties: Siem Car Carrier Pacific AS and Eukor Car Carriers Inc.

Filing Party: Ashley W. Craig Esq.; Venable LLP; 575 Seventh Street NW., Washington, DC 20004.

Synopsis: The agreement authorizes the parties to charter space in the trade between China and South Korea, on the one hand, and the U.S. West Coast, on the other hand.

Agreement No.: 201215–001.

Title: Port of Los Angeles Data Delivery Agreement.

Parties: City of Los Angeles Harbor Department; PierPass Inc.; APM Terminals Pacific; California United Terminals, Inc.; Eagle Marine Services, Ltd.; Seaside Transportation Services, LLC; Trapac Inc.; Yusen Terminals, Inc.; and West Basin Container Terminal, L.L.C.

Filing Party: David F. Smith, Esq., Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006–4007.

Synopsis: The amendment would extend the agreement's term and adjust the compensation provided for in the agreement.

By Order of the Federal Maritime Commission.

Dated: June 7, 2013.

Karen V. Gregory,

Secretary.

[FR Doc. 2013–13972 Filed 6–11–13; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than June 27, 2013.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *The Downing Family* consisting of D. Robert and Ardene K. Downing, Kamie Lynn-Downing and Gary L. Haynes, and Karey Downing and Todd R. Bishop, and Downing Family Investments, Inc., all of Indianola, Iowa together as a group acting in concert, to retain control of Central South Bancorporation, Inc., Indianola, Iowa, and thereby indirectly acquire Peoples Savings Bank, Indianola, Iowa.

Board of Governors of the Federal Reserve System, June 7, 2013.

Michael J. Lewandowski,

Assistant Secretary of the Board.

[FR Doc. 2013–13980 Filed 6–11–13; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Notice of Proposals To Engage in or To Acquire Companies Engaged in Permissible Nonbanking Activities

The companies listed in this notice have given notice under section 4 of the Bank Holding Company Act (12 U.S.C. 1843) (BHC Act) and Regulation Y, (12 CFR part 225) to engage *de novo,* or to acquire or control voting securities or assets of a company, including the companies listed below, that engages either directly or through a subsidiary or other company, in a nonbanking activity that is listed in § 225.28 of Regulation Y (12 CFR 225.28) or that the Board has determined by Order to be closely related to banking and permissible for bank holding companies. Unless otherwise noted, these activities will be conducted throughout the United States.

Each notice is available for inspection at the Federal Reserve Bank indicated. The notice also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether the proposal complies with the standards of section 4 of the BHC Act.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than July 8, 2013.

A. Federal Reserve Bank of New York (Ivan Hurwitz, Vice President) 33 Liberty Street, New York, New York 10045–0001:

1. Investors Bancorp, Inc. and Investors Bancorp, MHC., both of Short Hills, New Jersey, to acquire Gateway Community Financial Corporation, MHC, and Gateway Community Financial Corporation, and thereby acquire their wholly-owned subsidiary, GCF Bank, all of Sewell, New Jersey, and thereby engage in operating a savings association pursuant to Section 225.28(b)(ii) of Regulation Y.

Board of Governors of the Federal Reserve System, June 7, 2013.

Michael J. Lewandowski,

Assistant Secretary of the Board.

[FR Doc. 2013–13981 Filed 6–11–13; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice-MK–2013–05; Docket No. 2013–0002; Sequence 20]

The Presidential Commission on Election Administration (PCEA); Upcoming Public Advisory Meeting

AGENCY: Office of Government-wide Policy, U.S. General Services Administration (GSA).

ACTION: Meeting notice.

SUMMARY: The Presidential Commission on Election Administration (PCEA), a Federal Advisory Committee established in accordance with the Federal Advisory Committee Act (FACA), 5 U.S.C., App., and Executive Order 13639, as amended by EO 13644, will hold a meeting open to the public on Friday, June 28, 2013.

DATES: *Effective date:* June 12, 2013.

Meeting date: The meeting will be held on Friday, June 28, 2013, beginning at 9:00 a.m. eastern time, ending no later than 5:00 p.m.

FOR FURTHER INFORMATION CONTACT: Mr. Mark Nejbauer, Designated Federal Officer, President's Commission on Election Administration, GSA, 1776 G Street NW., Washington, DC 20006, email *mark.nejbauer@supportthevoter.gov.*

SUPPLEMENTARY INFORMATION:

Background: The PCEA was established to identify best practices and make recommendations to the President on the efficient administration of elections in order to ensure that all eligible voters have the opportunity to cast their ballots without undue delay, and to improve the experience of voters facing other obstacles in casting their ballots.

Agenda: The purpose of this meeting is for the PCEA to receive information to assist its members in collecting information and data relevant to its deliberations on the subjects set forth in Executive Order 13639, as amended.

The agenda will be as follows:

- Introductions & Statement of Plan for The Meeting
- Testimony by local, county and state election officials
- Receipt of reports by experts in some of the subject areas detailed in Executive Order 13639
- Comments by interested members of the public

Meeting Access: The PCEA will convene its meeting in the David W. Dyer U.S. Courthouse, 300 Northeast 1st Avenue, Miami, Florida 33132. This site is accessible to individuals with disabilities. The meeting may also be Webcast or made available via audio link. Please refer to PCEA's Web site, *http://www.supportthevoter.gov*, for the most up-to-date meeting agenda and access information.

Attendance at the Meeting: Individuals interested in attending the meeting must register in advance because of limited space. Please contact Mr. Nejbauer at the email address above to register to attend this meeting and obtain meeting materials. Materials may also be accessed online at *http://www.supportthevoter.gov*. To attend this meeting, please submit your full name, organization, email address, and phone number to Mark Nejbauer by 5:00 p.m. eastern standard time on Tuesday, June 25, 2013. Detailed meeting minutes will be posted within 90 days of the meeting.

Procedures for Providing Public Comments: In general, public comments will be posted on the PCEA Web site (see above). All comments, including attachments and other supporting materials, received are part of the public record and subject to public disclosure. Any comments submitted in connection with the PCEA meeting will be made available to the public under the provisions of the Federal Advisory Committee Act.

Contact Mark Nejbauer at *mark.nejbauer@supportthevoter.gov* to register to comment during the meeting's public comment period. Registered speakers/organizations will be allowed a maximum of 3 minutes each due to limited time for individual comments. Written copies providing expanded explanations of oral presentations are encouraged. Requests to comment at the meeting must be received by 5:00 p.m. eastern standard time on Tuesday, June 25, 2013.

The public is invited to submit written comments for this meeting until 5:00 p.m. eastern time on Tuesday, June 25, 2013, by either of the following method:

Electronic or Paper Statements: Submit electronic statements to Mr. Nejbauer, Designated Federal Officer at *mark.nejbauer@supportthevoter.gov;* or send three (3) copies of any written statements to Mr. Nejbauer at the PCEA GSA address above. Written comments not received by 5:00 p.m. eastern time on June 25, 2013 may be submitted but will not be considered at the June 28, 2013 meeting.

Dated: June 7, 2013.

Laura Auletta,

Acting Associate Administrator, Office of Government-wide Policy, General Services Administration.

[FR Doc. 2013–13959 Filed 6–11–13; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day–13–13LD]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639-7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395-5806. Written comments should be received within 30 days of this notice.

Proposed Project

Formative Research, Messages and Materials Development for NCBDDD—NEW—Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities (NCBDDD).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC), National Center on Birth Defects and Developmental Disabilities (NCBDDD), requests approval for a new generic information collection package that supports formative research in birth defects and developmental disabilities; human development and disabilities, and blood disorders. Identified priority diseases, disorders, and conditions included in this information collection activity include but are not limited to preconception health; autism spectrum disorders (ASDs) and other developmental disabilities; fetal alcohol spectrum disorders (FASDs); neural tube defects (spina bifida, anencephaly); muscular dystrophy; fragile X; deep vein thrombosis/pulmonary embolism (DVT/PE); sickle cell disease (SCD); attention-deficit/hyperactivity disorder (ADHD); and Tourette syndrome.

Birth defects affect 1 in 33 babies and are a leading cause of infant death in the United States. More than 5,500 infants die each year due to birth defects. Additionally, over 500,000 children are diagnosed with a developmental disability. With more information, the causes of these birth defects and developmental disabilities can be identified and action can be taken to protect children and to develop new

ways to help women have healthy babies.

The behavioral, clinical, and surveillance projects implemented by NCBDDD are the foundation upon which recommendations and guidelines are revised and updated. Formative research is the mechanism by which evidence is obtained for priority diseases in these three (3) health condition groups and by which recommendations and guidelines are revised and updated.

NCBDDD conducts formative research for developing new messages, materials, and strategies that respond to the changing epidemiology of these priority health conditions. A generic clearance mechanism would increase productivity of CDC programs and improve the quality of public health interventions and health communication programs.

Targeted audience members or representatives provide the information for developing clear and influential health messages, materials, and strategies that promote health and well-being. An integrated research effort is needed to fill in gaps of knowledge, awareness, screening, and prevention behaviors and could simultaneously work to reduce stigma surrounding these topics within special populations, explore cultural issues, and increase the demand for, and uptake of screening by health care providers.

Overall, these formative research activities are intended to provide information that will increase the success of the surveillance or research project through increasing response rates and decreasing response error thereby decreasing future data collection burden to the public.

It is estimated that approximately 8—10 individual projects will be processed each year using this mechanism. Data collection activities from a variety of groups are anticipated. Primary respondents will be Latina Spanish-dominant women of childbearing age (ages 18–45, both childless adult women and parents of young children) and individuals who identify as a member of a specified racial/ethnic/cultural minority community and thus considered hard to reach. Members of the educational, research, and public health community may also be targeted for their subject matter expertise.

This request is submitted to obtain Office of Management and Budget (OMB) clearance for three years. The estimates of annualized burden hours are based on past experience with recruitment and the administration of similar surveys and focus groups. It is estimated that 26,800 respondents will have to be screened annually to recruit the appropriate number of respondents for this data collection activity. Depending on the individual information collection request, information might be collected using the following modes: focus groups, in-person interviews (face-to-face or via telephone, paper-and-pencil questionnaires, or electronically. Electronic modes include handheld devices, computer-assisted self-interviews, computer-assisted personal interviews, web-based surveys, or other point-of-service collection devices.

Specific information will be provided with each individual project submission. The estimated annualized burden hours for this data collection activity are 16,550. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average hours per response
General public and health care providers	Screener	26,800	1	10/60
General public and health care providers	Consent Forms	10,000	1	5/60
General public and health care providers	Moderator's Guide	10,000	1	1
General public and health care providers	Surveys	5,000	1	15/60

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013–13899 Filed 6–11–13; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0578]

Agency Information Collection Activities; Proposed Collection; Comment Request; General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the collection of information relating to general licensing provisions for biologics license applications (BLAs), changes to an approved application, labeling, revocation and suspension, postmarketing studies status reports, and Forms FDA 356h and 2567.

DATES: Submit either electronic or written comments on the collection of information by August 12, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov.* Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR

1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

General Licensing Provisions: Biologics License Application, Changes to an Approved Application, Labeling, Revocation and Suspension, Postmarketing Studies Status Reports, and Forms FDA 356h and 2567 (OMB Control Number 0910–0338)—Extension

Under section 351 of the Public Health Service Act (42 U.S.C. 262), manufacturers of biological products must submit a license application for FDA review and approval before marketing a biological product in interstate commerce. Licenses may be issued only upon showing that the establishment and the products for which a license is desired meets standards prescribed in regulations designed to ensure the continued safety, purity, and potency of such products. All such licenses are issued, suspended, and revoked as prescribed by regulations in part 601 (21 CFR part 601).

Section 130(a) of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding a new provision (section 506B of the FD&C Act (21 U.S.C. 356b)) requiring reports of postmarketing studies for approved human drugs and licensed biological products. Section 506B of the FD&C Act provides FDA with additional authority to monitor the progress of postmarketing studies that applicants have made a commitment to conduct and requires the Agency to make publicly available information that pertains to the status of these studies. Under section 506B(a) of the FD&C Act, applicants that have committed to conduct a postmarketing study for an approved human drug or licensed biological product must submit to FDA a status report of the progress of the study or the reasons for the failure of the applicant to conduct the study. This report must be submitted within 1 year after the U.S. approval of the application and then annually until the study is completed or terminated.

A summary of the collection of information requirements follows:

Section 601.2(a) requires a manufacturer of a biological product to submit an application on forms prescribed for such purposes with accompanying data and information, including certain labeling information, to FDA for approval to market a product in interstate commerce. The container and package labeling requirements are provided under §§ 610.60 through 610.65 (21 CFR 610.60 through 610.65). The estimate for these regulations is included in the estimate under § 601.2(a) in table 1 of this document.

Section 601.5(a) requires a manufacturer to submit to FDA notice of its intention to discontinue manufacture of a product or all products. Section 601.6(a) requires the manufacturer to notify selling agents and distributors upon suspension of its license, and provide FDA of such notification.

Section 601.12(a)(2) requires, generally, that the holder of an approved BLA must assess the effects of a manufacturing change before distributing a biological product made with the change. Section 601.12(a)(4) requires, generally, that the applicant must promptly revise all promotional labeling and advertising to make it consistent with any labeling changes implemented. Section 601.12(a)(5) requires the applicant to include a list of all changes contained in the supplement or annual report; for supplements, this list must be provided in the cover letter. The burden estimates for § 601.12(a)(2) are included in the estimates for supplements (§§ 601.12(b) and (c)) and annual reports (§ 601.12(d)). The burden estimates for § 601.12(a)(4) are included in the estimates under § 601.12(f)(4) in table 1 of this document.

Sections 601.12(b)(1), (b)(3), (c)(1), (c)(3), (c)(5), (d)(1), and (d)(3) require applicants to follow specific procedures to submit information to FDA of any changes, in the product, production process, quality controls, equipment, facilities, or responsible personnel established in an approved license application. The appropriate procedure depends on the potential for the change to have a substantial, moderate, or minimal adverse effect on the identity, strength, quality, purity, or potency of the products as they may relate to the safety or effectiveness of the product. Under § 601.12(b)(4), an applicant may ask FDA to expedite its review of a supplement for public health reasons or if a delay in making the change described in it would impose an extraordinary hardship of the applicant. The burden estimate for § 601.12(b)(4) is minimal and included in the estimate under § 601.12(b)(1) and (b)(3) in table 1 of this document.

Section 601.12(e) requires applicants to submit a protocol, or change to a protocol, as a supplement requiring FDA approval before distributing the product. Section 601.12(f)(1), (f)(2), and (f)(3) requires applicants to follow specific procedures to report certain labeling changes to FDA. Section 601.12(f)(4) requires applicants to report to FDA advertising and promotional labeling and any changes.

Under § 601.14, the content of labeling required in 21 CFR 201.100(d)(3) must be in electronic format and in a form that FDA can process, review, and archive. This requirement is in addition to the provisions of §§ 601.2(a) and 601.12(f). The burden estimate for § 601.14 is minimal and included in the estimate under §§ 601.2(a) (BLAs) and 601.12(f)(1), (f)(2), and (f)(3) (labeling supplements and annual reports) in table 1 of this document.

Section 601.45 requires applicants of biological products for serious or life-threatening illnesses to submit to the Agency for consideration, during the pre-approval review period, copies of all promotional materials, including promotional labeling as well as advertisements.

In addition to §§ 601.2 and 601.12, there are other regulations in 21 CFR Parts 640, 660, and 680 that relate to information to be submitted in a license application or supplement for certain blood or allergenic products as follows: §§ 640.6; 640.17; 640.21(c); 640.22(c); 640.25(c); 640.56(c); 640.64(c); 640.74(a) and (b)(2); 660.51(a)(4); and 680.1(b)(2)(iii) and (d).

In table 1 of this document, the burden associated with the information collection requirements in the applicable regulations is included in the

burden estimate for §§ 601.2 and/or 601.12. A regulation may be listed under more than one subsection of § 601.12 due to the type of category under which a change to an approved application may be submitted.

There are also additional container and/or package labeling requirements for certain licensed biological products including: § 640.74(b)(3) and (4) for Source Plasma Liquid; § 640.84(a) and (c) for Albumin; § 640.94(a) for Plasma Protein Fraction; § 660.2(c) for Antibody to Hepatitis B Surface Antigen; § 660.28(a), (b), and (c) for Blood Grouping Reagent; § 660.35(a), (c through g), and (i through m) for Reagent Red Blood Cells; § 660.45 for Hepatitis B Surface Antigen; and § 660.55(a) and (b) for Anti-Human Globulin. The burden associated with the additional labeling requirements for submission of a license application for these certain biological products is minimal because the majority of the burden is associated with the requirements under §§ 610.60 through 610.65 or 21 CFR 809.10. Therefore, the burden estimates for these regulations are included in the estimate under §§ 610.60 through 610.65 in table 1 of this document. The burden estimates associated with § 809.10 are approved under OMB control number 0910–0485.

Section 601.25(b) requests interested persons to submit, for review and evaluation by an advisory review panel, published and unpublished data and information pertinent to a designated category of biological products that have been licensed prior to July 1, 1972. Section 601.26(f) requires that licensees submit to FDA a written statement intended to show that studies adequate and appropriate to resolve the questions raised about a biological product have been undertaken for a product if designated as requiring further study under the reclassification procedures. Under § 601.25(b), FDA estimates no further burden for this regulation, and therefore this regulation is not included in table 1 of this document. Under § 601.26(f), FDA estimates no burden for this regulation since there are no products designated to require further study and none are predicted in the future. However, FDA is using an estimate of 1 for calculation purposes. Based on the possible reclassification of a product, the labeling for the product may need to be revised, or a manufacturer, on its own initiative, may deem it necessary for further study. As a result, any changes to product labeling would be reported under the appropriate subsection of § 601.12.

Section 601.27(a) requires that applications for new biological products contain data that are adequate to assess the safety and effectiveness of the biological product for the claimed indications in pediatric subpopulations, and to support dosing and administration information. Section 601.27(b) provides that an applicant may request a deferred submission of some or all assessments of safety and effectiveness required under § 601.27(a) until after licensing the product for use in adults. Section 601.27(c) provides that an applicant may request a full or partial waiver of the requirements under § 601.27(a) with adequate justification. The burden estimates for § 601.27(a) are included in the burden estimate under § 601.2(a) in table 1 of this document since these regulations deal with information to be provided in an application.

Section 601.28 requires sponsors of licensed biological products to submit the information in § 601.28(a), (b), and (c) to the Center for Biologics Evaluation and Research (CBER) or to the Center for Drug Evaluation and Research (CDER) each year, within 60 days of the anniversary date of approval of the license. Section 601.28(a) requires sponsors to submit to FDA a brief summary stating whether labeling supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated. Section 601.28(b) requires sponsors to submit to FDA an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information. Section 601.28(c) requires sponsors to submit to FDA a statement on the current status of any postmarketing studies in the pediatric population performed by, on or behalf of, the applicant. If the postmarketing studies were required or agreed to, the status of these studies is to be reported under § 601.70 rather then under this section.

Sections 601.33 through 601.35 clarify the information to be submitted in an application to FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals. The burden estimates for §§ 601.33 through 601.35 are included in the burden estimate under § 601.2(a) in table 1 of this document since these regulations deal with information to be provided in an application.

Section 601.70(b) requires each applicant of a licensed biological product to submit annually a report to FDA on the status of postmarketing studies for each approved product application. Each annual postmarketing status report must be accompanied by a completed transmittal Form FDA 2252 (Form FDA 2252 approved under OMB control number 0910–0001). Under § 601.70(d), two copies of the annual report shall be submitted to FDA.

Sections 601.91 through 601.94 concern biological products for which human efficacy studies are not ethical or feasible. Section 601.91(b)(2) requires, in certain circumstances, such postmarking restrictions as are needed to ensure the safe use of the biological product. Section 601.91(b)(3) requires applicants to prepare and provide labeling with relevant information to patients or potential patients for biological products approved under part 601, subpart H, when human efficacy studies are not ethical or feasible (or based on evidence of effectiveness from studies in animals). Section 601.93 provides that biological products approved under subpart H are subject to the postmarketing recordkeeping and safety reporting applicable to all approved biological products. Section 601.94 requires applicants under subpart H to submit to the Agency for consideration during preapproval review period copies of all promotional materials including promotional labeling as well as advertisements. Under §§ 601.91(b)(2) and 601.93, any potential postmarketing reports and/or recordkeeping burdens would be included under the adverse experience reporting (AER) requirements under 21 CFR Part 600 (OMB control number 0910–0308). Therefore, any burdens associated with these requirements would be reported under the AER information collection requirements (OMB control number 0910–0308). The burden estimate for § 601.91(b)(3) is included in the estimate under §§ 610.60 through 610.65.

Section 610.9(a) requires the applicant to present certain information, in the form of a license application or supplement to the application, for a modification of any particular test method or manufacturing process or the conditions which it is conducted under the biologics regulations. The burden estimate for § 610.9(a) is included in the estimate under §§ 601.2(a) and 601.12(b) and (c) in table 1 of this document.

Section 610.11(g)(2) provides that a manufacturer of certain biological products may request an exemption from the general safety test (GST) requirements contained in subpart H. Under § 610.11(g)(2), FDA requires only those manufacturers of biological products requesting an exemption from the GST to submit additional information as part of a license application or supplement to an approved license application. Therefore,

the burden estimate for § 610.11(g)(2) is included in the estimate under §§ 601.2(a) and 601.12(b) in table 1 of this document.

Under § 610.15(d), the Director of CBER or the Director of CDER may approve, as appropriate, a manufacturer's request for exceptions or alternatives to the regulation for constituent materials. Manufacturers seeking approval of an exception or alternative must submit a request in writing with a brief statement describing the basis for the request and the supporting data.

Section 640.120 requires licensed establishments to submit a request for an exception or alternative to any requirement in the biologics regulations regarding blood, blood components, or blood products. A request for an exception or alternative must be submitted in accordance with § 601.12; therefore, the burden estimate for § 640.120 is included in the estimate under § 601.12(b) in table 1 of this document.

Section 680.1(c) requires manufacturers to update annually their license file with the list of source materials and the suppliers of the materials. Section 680.1(b)(3)(iv) requires manufacturers to notify FDA when certain diseases are detected in source materials.

Sections 600.15(b) and 610.53(d) require the submission of a request for an exemption or modification regarding the temperature requirements during shipment and from dating periods, respectively, for certain biological products. Section 606.110(b) (21 CFR 606.110(b)) requires the submission of a request for approval to perform plasmapheresis of donors who do not meet certain donor requirements for the collection of plasma containing rare antibodies. Under §§ 600.15(b), 610.53(d), and 606.110(b), a request for an exemption or modification to the requirements would be submitted as a supplement. Therefore, the burden hours for any submissions under §§ 600.15(b), 610.53(d), and 606.110(b) are included in the estimates under § 601.12(b) in table 1 of this document.

In July 1997, FDA revised Form FDA 356h ''Application to Market a New Drug, Biologic, or an Antibiotic Drug for Human Use'' to harmonize application procedures between CBER and CDER. The application form serves primarily as a checklist for firms to gather and submit certain information to FDA. As such, the form, now entitled ''Application to Market a New or Abbreviated New Drug or Biologic for Human Use'' helps to ensure that the application is complete and contains all the necessary information, so that delays due to lack of information may be eliminated. In addition, the form provides key information to FDA for efficient handling and distribution to the appropriate staff for review. The estimated burden hours for nonbiological product submissions to CDER using Form FDA 356h are approved under OMB control number 0910–0001 (an estimated 3,200 submissions × 24 hours = 76,800 hours).

Form FDA 2567 ''Transmittal of Labels and Circulars'' may be used by manufacturers of licensed biological products to submit labeling (e.g., circulars, package labels, container labels, etc.) and labeling changes for FDA review and approval. For advertisements and promotional labeling, manufacturers of licensed biological products may submit to CBER either Form FDA 2567 or 2253. Form FDA 2253 was previously used only by drug manufacturers regulated by CDER. In August of 1998, FDA revised and harmonized Form FDA 2253 so the form may be used to transmit specimens of promotional labeling and advertisements for biological products as well as for prescription drugs and antibiotics. The revised, harmonized form updates the information about the types of promotional materials and the codes that are used to clarify the type of advertisement or labeling submitted, clarifies the intended audience for the advertisements or promotional labeling (e.g., consumers, professionals, news services), and helps ensure that the submission is complete. Form FDA 2253 is approved under OMB control number 0910–0001.

Under tables 1 and 2 of this document, the numbers of respondents are based on the estimated annual number of manufacturers that submitted the required information to FDA or the number of submissions FDA received in fiscal year 2012. Based on information obtained from FDA's database systems, there are an estimated 323 licensed biologics manufacturers. The total annual responses are based on the estimated number of submissions (i.e., license applications, labeling and other supplements, protocols, advertising and promotional labeling, notifications) for a particular product received annually by FDA. The hours per response are based on information provided by industry and past FDA experience with the various submissions or notifications. The hours per response include the time estimated to prepare the various submissions or notifications to FDA, and, as applicable, the time required to fill out the appropriate form and collate the documentation. Additional information regarding these estimates is provided below as necessary.

Under §§ 601.2 and 601.12, the estimated hours per response are based on the average number of hours to submit the various submissions. The estimated average number of hours is based on the range of hours to complete a very basic application or supplement and a complex application or supplement.

Under section 601.6(a), the total annual responses are based on FDA estimates that establishments may notify an average of 20 selling agents and distributors of such suspension, and provide FDA of such notification. The number of respondents is based on the estimated annual number of suspensions of a biologic license.

Under §§ 601.12(f)(4) and 601.45, manufacturers of biological products may use either Form FDA 2567 or Form FDA 2253 to submit advertising and promotional labeling. Based on information obtained from FDA's database system, there were an estimated 10,758 submissions of advertising and promotional labeling.

Under §§ 601.28 and 601.70(b), FDA estimates that it takes an applicant approximately 24 hours (8 hours per study × 3 studies) annually to gather, complete, and submit the appropriate information for each postmarketing status report (approximately two to four studies per report) and the accompanied transmittal Form FDA 2252. Included in these 24 hours is the time necessary to prepare and submit two copies of the annual progress report of postmarketing studies to FDA under § 601.70(d).

Under § 610.15(d), FDA has received no submissions since the implementation of the final rule in April 2011. Therefore, FDA is estimating one respondent and one annual request to account for a possible submission to CBER or CDER of a request for an exception or alternative for constituent materials under § 610.15(d).

There were a total of 2,664 amendments to an unapproved application or supplement and resubmissions submitted using Form FDA 356h.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
601.2(a),[2] 610.60 through 610.65 [3]	2567/356h	25	1.8	45	860	38,700
601.5(a)	NA	8	1	8	* 0.33	2.64
601.6(a)	NA	1	1	1	* 0.33	0.33
601.12(a)(5)	NA	791	16.51	13,057	1	13,057
601.12(b)(1)/(b)(3)/(e) [4]	[2] 356h	174	4.01	698	80	55,840
601.12(c)(1)/(c)(3) [5]	[2] 356h	117	4.60	538	50	26,900
601.12(c)(5)	[2] 356h	18	1.61	29	50	1,450
601.12(d)(1)/(d)(3) [6]/(f)(3) [8]	[2] 356h	241	3.08	742	24	17,808
601.12(f)(1) [7]	2567	67	2.48	166	40	6,640
601.12(f)(2) [7]	2567	72	1.78	128	20	2,560
601.12(f)(4)/601.45 [9]	2567/2253	102	103.71	10,578	10	105,780
601.26(f)	NA	1	1	1	1	1
601.27(b)	NA	4	1	4	24	96
601.27(c)	NA	6	1	6	8	48
601.70(b) and (d)/601.28	2252	56	1.91	107	24	2,568
610.15(d)	NA	1	1	1	1	1
680.1(c)	NA	9	1	9	2	18
680.1(b)(3)(iv)	NA	1	1	1	2	2
Amendments/Resubmissions	356h	207	12.87	2,664	20	53,280
Total						324,752

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The reporting requirements under §§ 601.14, 601.27(a), 601.33, 601.34, 601.35, 610.9(a), 610.11(g)(2), 640.17, 640.25(c), 640.56(c), 640.74(b)(2), 660.51(a)(4), and 680.1(b)(2)(iii) are included in the estimate under § 601.2(a).
[3] The reporting requirements under §§ 601.93(b)(3), 640.74(b)(3) and (4), 640.84(a) and (c), 640.94(a), 660.2(c), 660.28(a), (b), and (c), 660.35(a), (c through g), and (i through m), 660.45, and 660.55(a) and (b) are included under §§ 610.60 through 610.65.
[4] The reporting requirements under §§ 601.12(a)(2) and (b)(4), 600.15(b), 610.9(a), 610.11(g)(2), 610.53(d), 606.110(b), 640.6, 640.17, 640.21(c), 640.22(c), 640.25(c), 640.56(c), 640.64(c), 640.74(a) and (b)(2), 640.120, and 680.1(d) are included in the estimate under § 601.12(b).
[5] The reporting requirements under §§ 601.12(a)(2), 610.9(a), 640.17, 640.25(c), 640.56(c), and 640.74(b)(2) are included in the estimate under § 601.12(c).
[6] The reporting requirement under § 601.12(a)(2) is included in the estimate under § 601.12(d).
[7] The reporting requirement under § 601.14 is included in the estimate under § 601.12(f)(1) and (f)(2).
[8] The reporting requirement under §§ 601.12(a)(4) and 601.14 is included in the estimate under § 601.12(f)(3).
[9] The reporting requirement under § 601.94 is included in the estimate under § 601.45.
* 20 minutes.

Under table 2, the estimated recordkeeping burden of 1 hour is based on previous estimates for the recordkeeping requirements associated with the AER system.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR Section	Number of respondents	Annual disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
601.6(a)	1	20	20	* 0.33	6.6

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* 20 minutes.

Dated: June 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13896 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0653]

Agency Information Collection Activities; Proposed Collection; Comment Request; Orphan Drugs; Common European Medicines Agency/ Food and Drug Administration Application Form for Orphan Medicinal Product Designation (Form FDA 3671)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on

the procedures by which sponsors of orphan drugs may request eligibility for the incentives by implementing a program as outlined in the Orphan Drug Act and the joint adoption by FDA and the European Medicines Agency (EMA) of the Common EMA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671).

DATES: Submit either electronic or written comments on the collection of information by August 12, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3794, *Jonnalynn.capezzuto@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Orphan Drugs; Common EMA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671)—21 CFR Part 316 (OMB Control Number 0910–0167)—Extension

Sections 525 through 528 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360aa through 360dd) give FDA statutory authority to do the following: (1) Provide recommendations on investigations required for approval of marketing applications for orphan drugs; (2) designate eligible drugs as orphan drugs; (3) set forth conditions under which a sponsor of an approved orphan drug obtains exclusive approval; and (4) encourage sponsors to make orphan drugs available for treatment on an ''open protocol'' basis before the drug has been approved for general marketing. The implementing regulations for these statutory requirements have been codified under part 316 (21 CFR part 316) and specify procedures that sponsors of orphan drugs use in availing themselves of the incentives provided for orphan drugs in the FD&C Act and sets forth procedures FDA will use in administering the FD&C Act with regard to orphan drugs. Section 316.10 specifies the content and format of a request for written recommendations concerning the non-clinical laboratory studies and clinical investigations necessary for approval of marketing applications. Section 316.12 provides that, before providing such recommendations, FDA may require results of studies to be submitted for review. Section 316.14 contains provisions permitting FDA to refuse to provide written recommendations under certain circumstances. Within 90 days of any refusal, a sponsor may submit additional information specified by FDA. Based on past experience, FDA estimates that there will be two respondents to §§ 316.10, 316.12, and 316.14 requiring 200 hours of human resources annually.

Section 316.20 specifies the content and format of an orphan drug application which includes requirements that an applicant document that the disease is rare (affects fewer than 200,000 persons in the United States annually) or that the sponsor of the drug has no reasonable expectation of recovering costs of research and development of the drug. Section 316.21 specifies content of a request for orphan drug designation required for verification of orphan-drug status. Section 316.26 allows an applicant to amend the applications under certain circumstances. The Common EMA/FDA Application Form for Orphan Medicinal Product Designation (Form FDA 3671) is intended to benefit sponsors who desire to seek orphan designation of drugs intended for rare diseases or conditions from both the European Commission and FDA by reducing the burden of preparing separate applications to meet the regulatory requirements in each jurisdiction. It highlights the regulatory cooperation between the United States and the European Union mandated by the Transatlantic Economic Council. FDA does not believe the new form will result in any increased burden on the respondents and therefore we estimate no additional burden. Based on past experience, FDA estimates there will be 214 respondents requiring 64,200 hours of human resources annually. Section 316.22 specifies requirement of a permanent resident agent for foreign sponsors. Based on past experience, FDA estimates 55 respondents requiring 110 hours of human resources annually. Section 316.27 specifies content of a change in ownership of orphan-drug designation. Based on past experience, FDA estimates 43 respondents requiring 215 hours of human resources annually. Section 316.30 requires submission of annual reports, including progress reports on studies, a description of the investigational plan, and a discussion of changes that may affect orphan status. Based on number of orphan-drug designations, the number of respondents is estimated as 1,652 requiring 4,956 hours of human resources annually. Finally, § 316.36 describes information required of sponsor when there is insufficient quantity of approved orphan drug. Based on past experience, FDA estimates 1 respondent requiring 45 hours of human resources annually.

The information requested will provide the basis for an FDA determination that the drug is for a rare disease or condition and satisfies the requirements for obtaining orphan drug status. Secondly, the information will describe the medical and regulatory history of the drug. The respondents to this collection of information are biotechnology firms, drug companies, and academic clinical researchers.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section and Form FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Content and format when seeking written recommendations; results of studies; amendments (§§ 316.10, 316.12, 316.14)	2	1	2	100	200
Content and format of a request for orphan-drug designation; request for verification of orphan-drug status; amendments (§§ 316.20, 316.21, 316.26) Form FDA 3671	214	2	428	150	64,200
Notifications of changes in agents (§ 316.22)	55	1	55	2	110
Submissions to change ownership of orphan-drug designation (§ 316.27)	43	1	43	5	215
Annual reports (§ 316.30)	1,652	1	1,652	3	4,956
Assurance of the availability of sufficient quantities of the orphan drug; holder's consent for the approval of other marketing applications for the same drug (§ 316.36)	1	3	3	15	45
Total					69,726

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 5, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13858 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0618]

Agency Information Collection Activities; Proposed Collection; Comment Request; Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for reporting and recordkeeping, general and specific requirements, and the availability of sample electronic products for manufacturers and distributors of electronic products.

DATES: Submit either electronic or written comments on the collection of information by August 12, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Electronic Products—21 CFR Parts 1002 Through 1010 (OMB Control Number 0910–0025)—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure of radiation from electronic products. The regulations issued under these authorities are listed in title 21 of the Code of Federal Regulations, chapter I, subpart J, parts 1000 through 1050 (21 CFR parts 1000 through 1050).

Section 532 of the FD&C Act directs the Secretary of the Department of Health and Human Services (the Secretary), to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the FD&C Act authorizes the Secretary

to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products. Section 534(g) of the FD&C Act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and section 535(e) and (f) of the FD&C Act directs the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliances with performance standards. Section 537(b) of the FD&C Act contains the authority to require manufacturers of electronic products to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

The regulations under parts 1002 through 1010 specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall. FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050.

FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the FD&C Act or were developed to aid the Agency in performing its obligations under the FD&C Act. The data reported to FDA and the records maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection:

- FDA Form 2579 ''Report of Assembly of a Diagnostic X-Ray System''
- FDA Form 2767 ''Notice of Availability of Sample Electronic Product''
- FDA Form 2877 ''Declaration for Imported Electronic Products Subject to Radiation Control Standards''
- FDA Form 3649 ''Accidental Radiation Occurrence (ARO)''
- FDA Form 3626 ''A Guide for the Submission of Initial Reports on Diagnostic X-Ray Systems and Their Major Components''
- FDA Form 3627 ''Diagnostic X-Ray CT Products Radiation Safety Report''
- FDA Form 3628 ''General Annual Report (Includes Medical, Analytical, and Industrial X-Ray Products Annual Report)''
- FDA Form 3629 ''Abbreviated Report''
- FDA Form 3630 ''Guide for Preparing Product Reports on Sunlamps and Sunlamp Products''
- FDA Form 3631 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Sunlamps and Sunlamp Products''
- FDA Form 3632 ''Guide for Preparing Product Reports on Lasers and Products Containing Lasers''
- FDA Form 3633 ''General Variance Request''
- FDA Form 3634 ''Television Products Annual Report''
- FDA Form 3635 ''Laser Light Show Notification''
- FDA Form 3636 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Laser and Laser Light Show Products''
- FDA Form 3637 ''Laser Original Equipment Manufacturer (OEM) Report''
- FDA Form 3638 ''Guide for Filing Annual Reports for X-Ray Components and Systems''
- FDA Form 3639 ''Guidance for the Submission of Cabinet X-Ray System Reports Pursuant to 21 CFR 1020.40''
- FDA Form 3640 ''Reporting Guide for Laser Light Shows and Displays''
- FDA Form 3147 ''Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device''
- FDA Form 3641 ''Cabinet X-Ray Annual Report''
- FDA Form 3642 ''General Correspondence''
- FDA Form 3643 ''Microwave Oven Products Annual Report''
- FDA Form 3644 ''Guide for Preparing Product Reports for Ultrasonic Therapy Products''
- FDA Form 3645 ''Guide for Preparing Annual Reports for Ultrasonic Therapy Products''
- FDA Form 3646 ''Mercury Vapor Lamp Products Radiation Safety Report''
- FDA Form 3647 ''Guide for Preparing Annual Reports on Radiation Safety Testing of Mercury Vapor Lamps''
- FDA Form 3659 ''Reporting and Compliance Guide for Television Products''
- FDA Form 3660 ''Guidance for Preparing Reports on Radiation Safety of Microwave Ovens''
- FDA Form 3661 ''Guide for the Submission of an Abbreviated Report on X-Ray Tables, Cradles, Film Changers, or Cassette Holders Intended for Diagnostic Use''
- FDA Form 3662 ''Guide for Submission of an Abbreviated Radiation Safety Report on Cephalometric Devices Intended for Diagnostic Use''
- FDA Form 3663 ''Abbreviated Reports on Radiation Safety for Microwave Products (Other Than Microwave Ovens)''
- FDA Form 3801 ''Guide for Preparing Initial Reports and Model Change Reports on Medical Ultraviolet Lamps and Products Containing Such Lamps''

The respondents to this information collection are electronic product and x-ray manufacturers, importers, and assemblers. The burden estimates were derived by consultation with FDA and industry personnel, and are based on data collected from industry, including recent product report submissions. An evaluation of the type and scope of information requested was also used to derive some time estimates.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
Product reports—1002.10(a)–(k).	3626—Diagnostic x-ray	1,500	1.1	1,650	24	39,600
	3627—CT x-ray.					
	3639—Cabinet x-ray.					
	3632—Laser.					
	3640—Laser light show.					

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity/21 CFR section	FDA form	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
	3630—Sunlamp. 3646—Mercury vapor lamp. 3644—Ultrasonic therapy. 3659—TV. 3660—Microwave oven. 3801—UV lamps.					
Product safety or testing changes—1002.11(a)–(b).	.....	1,000	1.5	1,500	0.5	750
Abbreviated reports—1002.12.	3629—General abbreviated report. 3661—X-ray tables, etc. 3662—Cephalometric device. 3663—Microwave products (non-oven).	60	2	120	5	600
Annual reports—1002.13(a)–(b).	3628—General ..... 3634—TV. 3638—Diagnostic x-ray. 3641—Cabinet x-ray. 3643—Microwave oven. 3636—Laser. 3631—Sunlamp. 3647—Mercury vapor lamp. 3645—Ultrasonic therapy.	1,500	1	1,500	18	27,000
Quarterly updates for new models—1002.13(c).	.....	3	4	12	0.5	6
Accidental radiation occurrence reports—1002.20.	3649—ARO	15	6	90	2	180
Exemption requests—1002.50(a) and 1002.51.	3642—General correspondence.	10	1	10	1	10
Product and sample information—1005.10.	2767—Sample product	5	1	5	0.1	1
Identification information and compliance status—1005.25.	2877—Imports declaration	1,000	20	20,000	0.2	4,000
Alternate means of certification—1010.2(d).	.....	1	2	2	5	10
Variance—1010.4(b)	3633—General variance request. 3147—Laser show variance request. 3635—Laser show notification.	350	1	350	1.2	420
Exemption from performance standards—1010.5(c) and (d).	.....	1	1	1	22	22
Alternate test procedures—1010.13.	.....	1	1	1	10	10
Report of assembly of diagnostic x-ray components—1020.30(d), (d)(1), and (d)(2).	2579—Assembler report ...	2,000	14	28,000	0.30	8,400
Microwave oven exemption from warning labels—1030.10(c)(6)(iv).	.....	1	1	1	1	1
Laser products registration—1040.10(a)(3)(i).	3637—Original equipment manufacturer (OEM) report.	50	3	150	3	450
Total	.....	.....	.....	.....	.....	81,460

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per record-keeping	Total hours [2]
Manufacturers records—1002.30 and 1002.31(a)	1,600	1,650	2,640,000	0.12	316,800
Dealer/distributor records—1002.40 and 1002.41	3,000	50	150,000	0.05	7,500
Information on diagnostic x-ray systems—1020.30(g)	50	1	50	0.5	25
Laser products distribution records—1040.10(a)(3)(ii)	50	1	50	1	50
Total					324,375

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total Hours [2]
Technical and safety information for users—1002.3	1	1	1	12	12
Dealer/distributor records—1002.40 and 1002.41	50	3	150	1	150
Television receiver critical component warning—1020.10(c)(4)	1	1	1	1	1
Cold cathode tubes—1020.20(c)(4)	1	1	1	1	1
Information on diagnostic x-ray systems—1020.30(g)	100	2	200	55	11,000
Statement of maximum line current of x-ray systems—1020.30(g)(2)	15	1	15	10	150
Diagnostic x-ray system safety and technical information—1020.30(h)(1)–(h)(4)	100	2	200	200	40,000
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5)–(h)(6) and 1020.32(a)(1), (g), and (j)(4)	15	2	30	25	750
CT equipment—1020.33(c)–(d), (g)(4), and (j)	25	2	50	150	7,500
Cabinet x-ray systems information—1020.40(c)(9)(i)–(c)(9)(ii)	30	2	60	40	2,400
Microwave oven radiation safety instructions—1030.10(c)(4)	1	1	1	20	20
Microwave oven safety information and instructions—1030.10(c)(5)(i)–(c)(5)(iv)	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii)	1	1	1	1	1
Laser products information—1040.10(h)(1)(i)–(h)(1)(vi)	1,000	1.2	1,200	20	24,000
Laser product service information—1040.10(h)(2)(i)–(h)(2)(ii)	1,000	1.2	1,200	20	24,000
Medical laser product instructions—1040.11(a)(2)	35	1	35	10	350
Sunlamp products instructions—1040.20	10	5	50	10	500
Mercury vapor lamp labeling—1040.30(c)(1)(ii)	2	1	2	1	2
Mercury vapor lamp permanently affixed labels—1040.30(c)(2)	2	1	2	1	2
Ultrasonic therapy products—1050.10(d)(1)–(d)(4), (f)(1), and (f)(2)(iii)	5	1	5	56	280
Total					111,139

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

The following requirements are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA: Sections 1002.31(c), 1003.10(a)–(c), 1003.11(a)(3) and (b), 1003.20(a)–(h), 1003.21(a)–(d), 1003.22(a) and (b), 1003.30(a) and (b), 1003.31(a) and (b), 1004.2(a)–(i), 1004.3(a)–(i), 1004.4(a)–(h), 1005.21(a)–(c), and 1005.22(b). These requirements apply to the collection of information during the conduct of investigations or audits (5 CFR 1320.4).

The following labeling requirements are not subject to review under the PRA because they are a public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public (5 CFR 1320.3(c)(2)): Sections 1030.10(c)(6); 1040.10(g); 1040.20(d)(1)(i), (d)(2)(i), and (d)(2)(iii); and 1040.30(c)(1).

Dated: June 6, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13855 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0663]

Agency Information Collection Activities; Proposed Collection; Comment Request: Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection resulting from investigational new drug (IND) safety reporting requirements and safety reporting requirements for bioavailability and bioequivalence studies.

DATES: Submit either electronic or written comments on the collection of information by August 12, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane., rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans—(OMB Control Number 0910–0672)—Extension

In the **Federal Register** of September 29, 2010 (75 FR 59935), FDA published a document entitled ''Investigational New Drug Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans.'' The document clarified the Agency's expectations for timely review, evaluation, and submission of relevant and useful safety information and implemented internationally harmonized definitions and reporting standards for IND safety reports. The document also required safety reporting for bioavailability and bioequivalence studies. The document was intended to improve the utility of IND safety reports, expedite FDA's review of critical safety information, better protect human subjects enrolled in clinical trials, and harmonize safety reporting requirements internationally.

The rulemaking included the following information collection under the PRA that was not already included in 21 CFR 312.32 and approved under OMB control number 0910–0014.

Section 312.32(c)(1)(ii) and (c)(1)(iii) requires reporting to FDA, in an IND safety report, of potential serious risks from clinical trials within 15 calendar days for findings from epidemiological studies, pooled analyses of multiple studies, or other clinical studies that suggest a significant risk in humans exposed to the drug.

Section 312.32(c)(1)(iii) specifies the requirements for reporting to FDA in an IND safety report potential serious risks from clinical trials within 15 calendar days for findings from in vitro testing that suggest a significant risk to humans. FDA estimates that approximately 100 sponsors spend a total of approximately 12 hours per report to prepare and submit approximately 600 reports annually.

Section 312.32(c)(1)(iv) requires reporting to FDA in an IND safety report within 15 calendar days of any clinically important increase in the rate of occurrence of serious suspected adverse reactions over that listed in the protocol or investigator brochure. FDA estimates that approximately 10 sponsors spend a total of approximately 12 hours per report to prepare and submit approximately 10 reports annually.

The rulemaking also included new information collection under the PRA by requiring safety reporting for bioavailability and bioequivalence studies (21 CFR 320.31(d)). FDA estimates that approximately 10 sponsors spend a total of approximately 14 hours per report to prepare and submit approximately 200 reports annually.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
320.31(d) Bioavailability and Bioequivalence Safety Reports	10	20	200	14	2,800
312.32(c)(1)(ii) and (c)(1)(iii) IND Safety Reports	100	6	600	12	7,200
312.32(c)(1)(iv) IND Safety Reports	10	1	10	12	120
Total					10,120

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: June 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13904 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–M–0036, FDA–2013–M–0205, FDA–2013–M–0255, FDA–2013–M–0281, FDA–2013–M–0282, and FDA–2013–M–0343]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the Agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Nicole Wolanski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1650, Silver Spring, MD 20993–0002, 301–796–6570.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with sections 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the FD&C Act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2013, through March 31, 2013. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2013, THROUGH MARCH 31, 2013

PMA No., docket No.	Applicant	Trade name	Approval date
P110014, FDA–2013–M–0036	Dune Medical Devices, Inc	MarginProbe System	December 27, 2012.
H110002, FDA–2013–M–0205	Second Sight Medical Products, Inc	Argus™ II Retinal Prosthesis System	February 13, 2013.
P110032, FDA–2013–M–0282	Lombard Medical	Aorfix AAA Flexible Stent Graft System	February 14, 2013.
P040046, FDA–2013–M–0255	Allergan	Natrelle® 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants.	February 20, 2013.
P110013/S005, FDA–2013–M–0343	Medtronic Vascular, Inc	Resolute Integrity Zotarolimus-Eluting Coronary Stent System.	February 22, 2013.
P100030, FDA–2013–M–0281	Tenaxis Medical, Inc	ArterX Surgical Sealant	March 1, 2013.

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/default.htm.*

Dated: June 7, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–13905 Filed 6–11–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Evaluation and Initial Assessment of HRSA Teaching Health Centers. OMB No. 0915–xxxx—New.

Abstract: Section 5508 of the Affordable Care Act of 2010 amended section 340H of the Public Health Service Act to establish the Teaching Health Center Graduate Medical Education program to support the expansion of new and existing primary care residency training programs in community-based settings. The primary goals of this program are to increase the production of primary care doctors who are well prepared to practice in community settings, particularly with underserved populations, and to improve the overall number and geographic distribution of primary care providers.

To ensure these goals are achieved, the George Washington University (GW) will conduct an evaluation of the training, administrative and organizational structures, clinical service, challenges, innovations, costs associated with training, and outcomes of Teaching Health Centers (THCs). GW has developed a program data collection tool that assesses basic organizational and training characteristics of the programs (including program specialty, numbers trained, training sites, educational partners, and residency program financing), educational initiatives (particularly around training for changing health care delivery systems and community experiences), and health center characteristics (including current workforce and vacancies, clinical service provided by residents, and participation in workforce programs such as the National Health Service Corps).

Questionnaires have also been developed for implementation with all THC matriculating residents, graduating residents, and graduated residents at one year post-graduation. The matriculation questionnaire aims to collect background information on THC residents to better understand the characteristics of individuals who apply and are accepted to THC programs. The graduation questionnaire collects information on career plans. The alumni questionnaire collects information on career outcomes (including practice in primary care and in underserved settings) following graduation as well as feedback on the quality of training.

Statute requires that THC programs report annually on the types of primary care resident approved training programs that the THCs provided for residents, the number of approved training positions for residents, the number of residents who completed their residency training at the end of the academic year and care for vulnerable populations, and any other information as deemed appropriate by the Secretary. The described data collection activities will serve to meet this statutory requirement for the THC programs in a uniform and consistent manner and will allow comparisons of this group to other trainees in non-THC programs.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Program Data Collection Tool	40	1	40	8	320
THC Graduate Survey	200	1	200	0.33	66
THC Matriculant Survey	200	1	200	0.25	50
THC Graduation Survey	200	1	200	0.25	50
Total	640		640		486

Dated: June 6, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–13918 Filed 6–11–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Health Education Assistance Loan (HEAL) Program: Physician's Certification of Borrower's Total and Permanent Disability Form (OMB No. 0915–0204)—Extension

Abstract: The Health Education Assistance Loan (HEAL) program provided federally-insured loans to students in schools of allopathic medicine, osteopathic medicine, dentistry, veterinary medicine, optometry, podiatric medicine, pharmacy, public health, allied health, or chiropractic, and graduate students in health administration or clinical psychology through September 30, 1998. Eligible lenders, such as banks, savings and loan associations, credit unions, pension funds, state agencies, HEAL schools, and insurance companies made new refinanced HEAL loans which are insured by the federal government against loss due to borrower's death, disability, bankruptcy, and default. The basic purpose of the program was to assure the availability of funds for loans to eligible students who needed to borrow money to pay for their educational loans. Currently, the program monitors the federal liability and assists in default prevention activities.

The HEAL borrower, the borrower's physician, and the holder of the loan completes the Physician's Certification form to certify that the HEAL borrower meets the total and permanent disability provisions. The Department of Health and Human Services uses this form to obtain detailed information about disability claims which includes the following: (1) The borrower's consent to release medical records to the Department of Health and Human Services and to the holder of the borrower's HEAL loans, (2) pertinent information supplied by the certifying physician, (3) the physician's certification that the borrower is unable to engage in any substantial gainful activity because of a medically determinable impairment that is expected to continue for a long and indefinite period of time or to result in death, and (4) information from the lender on the unpaid balance. Failure to submit the required documentation will result in disapproval of a disability claim. No changes have been made to the current form.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Type of respondent	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Borrower	30	1	30	.08	2
Physician	30	1	30	.5	15
Loan Holder	15	2	30	.17	5
Total	75		90		22

Dated: June 6, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–13923 Filed 6–11–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received within 60 days of this notice.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Black Lung Clinics Program Performance Measures OMB No. 0915–0292—Extension.

Abstract: The Office of Rural Health Policy (ORHP), Health Resources and Services Administration, conducts an annual data collection of user information for the Black Lung Program, which has been ongoing, with OMB, approval since 2004. The purpose of the Black Lung Clinic Program is to improve the health status of coal workers by providing services to minimize the effects of respiratory and pulmonary impairments of coal miners, including treatment required in the management of problems associated with black lung disease, which improves the miner's quality of life and reduces economic costs associated with morbidity and mortality arising from pulmonary diseases. Collecting this data will provide HRSA information on how well each grantee is meeting the needs of active and retired miners in their communities.

Need and Proposed Use of the Information: Data from the annual report will provide quantitative information about the clinics, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, and occupation type); (b) the characteristics of services provided (medical encounters, non-medical encounters, benefits counseling, or outreach); and, (c) the number of patients served. This assessment will enable HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It will also ensure that funds are effectively used to provide services that meet the target population needs.

Likely Respondents: Black Lung Clinics Program Grantees.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Black Lung Clinics Program Measures	15	1	15	10.0	150
Total	15	1	15	10.0	150

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Dated: June 6, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–13915 Filed 6–11–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork

Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received within 30 days of this notice.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Primary Care Faculty Development Initiative.

OMB No. 0915–xxxx—New.

Abstract: HRSA's Bureau of Health Professions, Division of Medicine and Dentistry, has contracted with Oregon Health and Science University (OHSU), contract HHSH250201200023C, to conduct the planning, execution, and evaluation of a nationally based, longitudinal Primary Care Faculty Development Initiative (PCFDI) demonstration project. OHSU has developed web-based survey instruments which will be used to evaluate the effectiveness of the planned curriculum and its implementation and to make recommendations to improve teaching and competency assessment in primary care educational activities. The two web-based surveys are Irvine's Leadership Behavior Survey and the Faculty Skill & Program Feasibility Survey. The objectives of the survey instruments are to assess the feasibility and acceptability of an inter-disciplinary faculty development pilot program targeting primary care physicians, to measure the leadership skills of PCFDI faculty participants, and to assess the initial impact of faculty receiving training from an inter-disciplinary faculty development pilot program on their perception of skill development in the core content areas of leadership, change management, teamwork, panel or population management, competency assessment, and clinical microsystems.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Responses per respondent	Total responses	Hours per response	Total burden hours
Irvine's Leadership Behavior Survey	36	1	36	.167	6
Faculty Skill & Program Feasibility Survey	36	1	36	.25	9
Total	72	1	72		15

Dated: June 6, 2013.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2013–13929 Filed 6–11–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Discretionary Grant Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice of Class Deviation from Competition Requirements for the Maternal and Child Health Bureau's (MCHB) Family-to-Family Health Information Centers (F2F HIC) Program (H84).

SUMMARY: HRSA will be issuing non-competitive awards under the Family-to-Family Health Information Centers Program. Approximately $4.9M will be made available in the form of a grant to current grantees (see below) during the budget period of 6/1/2013—5/31/2014. This will provide for an extension of the program for one year, as provided for in section 624 of the American Taxpayer Relief Act of 2012 (Pub. L. 112–240) (ATRA) with the least disruption to the states, communities, and constituencies that currently receive assistance and services from these grantees.

SUPPLEMENTARY INFORMATION: Intended Recipients of the Awards: The 51 incumbent grantees of record (listed below).

Amount of the Non-Competitive Awards: Up to $95,700 per grantee.

CFDA Number: 93.504.

Period of Supplemental Funding: 6/1/2013–5/31/2014.

Authority: Section 501(c)(1) of the Social Security Act, as amended.

Justification: The F2F HIC program provides grants to family-run/staffed organizations to ensure families of children with special health care needs have access to adequate information about health and community resources to facilitate informed and shared decision-making around their children's health care. F2F HICs were originally authorized under the Budget Deficit Reduction Act of 2005 (Pub. L. 109–171). Congress specified that there be a family-run/staffed center in each state and the District of Columbia that, among other tasks, assists families of children with special health care needs to make informed choices about health care in order to promote good treatment decisions, cost effectiveness, and improved health outcomes; and provides information and educational opportunities for families, their health professionals, schools, and other appropriate entities. The earlier law was later amended by the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148), which made funding available until fiscal year (FY) 2012. As the end of the F2F HIC project period

quickly approached and continued funding was not provided in the President's Budget for FY 2013, MCHB prepared for closeout of the program.

Section 624 of the ATRA extended the F2F HICs through FY 2013. Under typical circumstances, the project period for the grantees would end on May 31, 2013, and a robust competitive process would take place. As the program's extension is only for one year, MCHB would not have sufficient time to conduct a robust competition and appropriately continue these grants without a break in the grant. MCHB proposes to extend the project periods of these grants by 12 months to properly respond to direction of the F2F HIC program's extension, enacted in the ATRA. This will provide sufficient fiscal resources to continue programmatic activities as outlined in program authorization with the least disruption to the states, communities, and the MCHB constituencies that currently receive assistance and services from these grantees.

FOR FURTHER INFORMATION CONTACT: LaQuanta Smalley, Integrated Services Branch, Division of Services for Children with Special Health Needs, Maternal and Child Health Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 13–61, Rockville, MD 20857; 301.443.2370; *lsmalley@hrsa.gov.*

MATERNAL AND CHILD HEALTH BUREAU SELECTED GRANT PROGRAMS EXTENSIONS WITH FUNDING

Grantee/Organization name	Grant No.	State	FY 2012 Authorized funding level	Revised project end date
Stone Soup Group	H84MC12893	AK	$95,700	31–May–2014.
Family Voices of Alabama Inc.	H84MC12901	AL	95,700	31–May–2014.
Arkansas Disability Coalition	H84MC12900	AR	95,700	31–May–2014.
Raising Special Kids	H84MC07942	AZ	95,700	31–May–2014.
Support for Families of Children w/Disabilities	H84MC07943	CA	95,700	31–May–2014.
Colorado Nonprofit Development Center	H84MC15142	CO	95,700	31–May–2014.
PATH Parent to Parent/Family Voices of CT	H84MC21663	CT	95,700	31–May–2014.
Advocates for Justice and Education, Inc.	H84MC21661	DC	95,700	31–May–2014.
Delaware Family Voices, Inc.	H84MC21662	DE	95,700	31–May–2014.
Family Network on Disabilities of Florida, Inc.	H84MC21660	FL	95,700	31–May–2014.
Parent to Parent of Georgia, Inc.	H84MC07947	GA	95,700	31–May–2014.
Hawaii Pediatric Association Research & Education Foundation	H84MC07999	HI	95,700	31–May–2014.
ASK Resource Center	H84MC24065	IA	95,700	31–May–2014.
Idaho Parents Unlimited Inc.	H84MC12896	ID	95,700	31–May–2014.
The Arc of Illinois	H84MC06873	IL	95,700	31–May–2014.
Family Voices Indiana	H84MC21659	IN	95,700	31–May–2014.
Families Together, Inc.	H84MC09487	KS	95,700	31–May–2014.
Commission for CSHCN	H84MC12897	KY	95,700	31–May–2014.
Bayou Land Families Helping Families	H84MC08043	LA	95,700	31–May–2014.
Federation for Children with Special Needs	H84MC08005	MA	95,700	31–May–2014.
The Parent's Place of Maryland	H84MC07946	MD	95,700	31–May–2014.
Maine Parent Federation	H84MC00003	ME	95,700	31–May–2014.
SEMHA PPA FCCYSHCN	H84MC09365	MI	95,700	31–May–2014.
PACER Center, Inc.	H84MC00005	MN	95,700	31–May–2014.
Curators, University of Missouri	H84MC09484	MO	95,700	31–May–2014.
University of Southern Mississippi	H84MC07948	MS	95,700	31–May–2014.
Parent's Let's Unite for Kids	H84MC09367	MT	95,700	31–May–2014.
Exceptional Children's Assistance Center	H84MC08000	NC	95,700	31–May–2014.
Family Voices of North Dakota, Inc	H84MC07992	ND	95,700	31–May–2014.
PTI Nebraska	H84MC08009	NE	95,700	31–May–2014.
NH Coalition for Citizens w/Disabilities	H84MC09488	NH	95,700	31–May–2014.
Statewide Parent Advocacy Network of NJ	H84MC07997	NJ	95,700	31–May–2014.
Parents Reaching Out to Help	H84MC08007	NM	95,700	31–May–2014.
Family TIES of Nevada, Inc.	H84MC08001	NV	95,700	31–May–2014.
Parent to Parent of NYS	H84MC08006	NY	95,700	31–May–2014.
Family Voices of Ohio	H84MC12903	OH	95,700	31–May–2014.
The Oklahoma Family Network, Inc.	H84MC09368	OK	95,700	31–May–2014.
Oregon Health and Science University	H84MC21658	OR	95,700	31–May–2014.
Parent Education & Advocacy Leadership Center	H84MC07998	PA	95,700	31–May–2014.
Rhode Island Parent Information Network, Inc.	H84MC08002	RI	95,700	31–May–2014.
Family Connection of South Carolina, Inc.	H84MC12895	SC	95,700	31–May–2014.
South Dakota Parent Connection, Inc.	H84MC07994	SD	95,700	31–May–2014.
Tennessee Disability Coalition	H84MC00004	TN	95,700	31–May–2014.
Texas Parent to Parent	H84MC07993	TX	95,700	31–May–2014.
Utah Parent Center	H84MC07996	UT	95,700	31–May–2014.
Virginia Commonwealth University	H84MC09486	VA	95,700	31–May–2014.
Vermont Family Network	H84MC21657	VT	95,700	31–May–2014.
Washington PAVE	H84MC09369	WA	95,700	31–May–2014.
Family Voices of Wisconsin, Inc.	H84MC21690	WI	95,700	31–May–2014.
West Virginia Parent Training and Information, Inc.	H84MC12898	WV	95,700	31–May–2014.
University of Wyoming	H84MC24069	WY	95,700	31–May–2014.

Dated: June 5, 2013.

Mary K. Wakefield,

Administrator.

[FR Doc. 2013–13941 Filed 6–11–13; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 207 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

Live Attenuated RSV Vaccines Based on Codon-Pair Deoptimization

Description of Technology: The technology includes patent rights and related materials for live attenuated viruses that can be used as a prophylactic vaccine against respiratory syncytial virus. The viruses are generated using codon-pair deoptimization techniques of the RSV polymerase ORF alone or together with the NS1, NS2, N, P, M, SH, G, and F ORFs, rendering the virus temperature sensitive. Experimental growth data for one such virus in mice and in African Green Monkeys demonstrates in vivo growth attenuation.

Potential Commercial Applications:

- Prophylactic vaccine
- Childhood and elder vaccine

Competitive Advantages:

- Live attenuated
- Codon deoptimized

Development Stage:

- Pre-clinical
- In vivo data available (animal)

Inventors: Peter Collins, Cyril Le Nouen, Linda Brock, Ursula Buchholz (NIAID)

Publications:

1. Collins PL, Melero JA. Progress in understanding and controlling respiratory syncytial virus: still crazy after all these years. Virus Res. 2011 Dec;162(1–2):80–99. [PMID 21963675]
2. Buchan JR, et al. tRNA properties help shape codon pair preferences in open reading frames. Nucleic Acids Res. 2006 Feb 9;34(3):1015–27. [PMID 16473853]

Intellectual Property:

- HHS Reference No. E–080–2013/0—US Provisional Patent Application No. 61/762,768 filed 08 Apr 2013
- HHS Reference No. E–080–2013/1—US Provisional Patent Application No. 61/794,155 filed 15 Mar 2013

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov.*

Improved Personalized Cancer Immunotherapy: Rapid Selection of Tumor-Reactive T Cells Based on Expression of Specific Cell Surface Markers

Description of Technology: Scientists at NIH have identified a process to select highly tumor-reactive T cells from a patient tumor sample based on the expression of four specific T cell surface markers: programmed cell death protein 1 (PD–1; CD279), 4–1BB (CD137), T cell Ig- and mucin-domain-containing molecule-3 (TIM–3), and/or lymphocyte activation gene 3 (LAG–3). After this enriched population of tumor fighting T cells, primarily tumor infiltrating lymphocytes (TIL), is selected and expanded to large quantities, it gets re-infused into the patient via an adoptive cell transfer (ACT) regimen. The key finding for this process is that the most tumor-reactive TIL found in a bulk population of cells obtained from a patient tumor sample reliably exhibit high expression of one or more of these four markers. By selecting cancer attacking TIL from a patient's tumor based on these markers prior to re-infusion, in vitro culture time is reduced to grow up the desired T cells and a more effective anti-cancer T cell product can be produced in comparison to previous TIL immunotherapy approaches.

This new method for selecting tumor-reactive T cells/TIL from tumor samples should help TIL immunotherapy become more GMP compliant and allow greater standardized of the TIL production process to enable more widespread utilization of this personalized cancer treatment approach outside of NIH.

Potential Commercial Applications:

- Personalized ACT immunotherapy to treat human cancers using T cells obtained from a tumor sample
- Possible integration into a standard procedure for obtaining tumor-reactive T cells/TIL from a tumor as part of a GMP-compliant TIL manufacturing process that gains regulatory approval as a personalized cancer treatment option
- The immunotherapy component of a combination cancer therapy regimen targeting specific tumor antigens in individual patients
- More rapid tumor-reactive T cell culturing process for laboratory testing

Competitive Advantages:

- Simpler: Tumor-reactive T cells/TIL can be selected for ACT from a bulk population derived from a tumor sample using common laboratory techniques
- More rapid: Selection of T cells/TIL based on expression of specific cell surface markers will reduce the culture time for these T cells before re-infusion into the patient to fight the tumor
- Less screening: This selection method eliminates the need to screen T cells/TIL for autologous tumor recognition before re-infusion into the patient

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: Alena Gros and Steven A. Rosenberg (NCI)

Intellectual Property: HHS Reference No. E–059–2013/0—US Patent Application No. 61/771,247 filed 01 March 2013; PCT Patent Application No. PCT/US2013/038799 filed 30 April 2013

Related Technologies:

- HHS Reference No. E–085–2013/0—US Patent Application No. 61/771,251; PCT Patent Application No. PCT/US2013/038813
- HHS Reference No. E–273–2009/0—US Patent No. 8,383,099; US Patent Application No. 13/742,541
- HHS Reference No. E–275–2002/1—US Patent No. 8,034,334; US Patent No. 8,287,857; Foreign counterparts in Europe, Canada, and Australia

Licensing Contact: Samuel E. Bish, Ph.D.; 301–435–5282; *bishse@mail.nih.gov*

Collaborative Research Opportunity: The National Cancer Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize adoptive transfer of tumor infiltrating lymphocytes (TIL) for cancers other than melanoma. For collaboration opportunities, please

contact Steven A. Rosenberg, M.D., Ph.D., at *sar@nih.gov* or 301–496–4164.

Diagnostic Assays for the Detection of Thyroid Cancer

Description of Technology: NIH scientists have developed two novel methods for distinguishing malignant from benign thyroid biopsy samples. Midkine and pleiotrophin, both low molecular weight growth factors, are over-expressed in many cancerous tissues. NIH researchers have developed ELISA assays to quantify the amount of midkine and pleiotrophin present in thyroid tissue samples. Levels of both growth factors are substantially higher in fine needle aspirates from thyroid cancers than from benign thyroid nodules. Application of this technique for the identification of thyroid cancer represents a first-in-class diagnostic for this disease.

Thyroid cancer represents a disease particularly amenable to improved methods of diagnosis. Thyroid nodules are very common in the adult population. To determine whether nodules are malignant, current practice involves obtaining a needle biopsy which is inspected microscopically. The resulting findings are subjective and often inconclusive, leading to unnecessary surgery. Therefore, there is a need for methods such as the present invention to improve diagnostic accuracy.

Potential Commercial Applications: A diagnostic kit for the detection of thyroid cancer.

Competitive Advantages:

- High assay sensitivity permits the use of small tissue samples (e.g., fine needle aspirates of nodules)
- Assay can incorporate commercially-available midkine or pleiotrophin antibodies.
- Assay relies on proven ELISA detection technology.

Development Stage:

- In vivo data available (animal)
- Clinical

Inventors: Jeffrey Baron and Youn Hee Jee (NICHD)

Intellectual Property:

- HHS Reference No. E–016–2013/0—US Application No. 61/728,624 filed 20 Nov 2012
- HHS Reference No. E–016–2013/1—US Application No. 61/815,342 filed 24 Apr 2013

Licensing Contact: Sabarni Chatterjee, Ph.D., MBA; 301–435–5587; *chatterjeesa@mail.nih.gov*

Collaborative Research Opportunity: The National Institute of Child Health and Human Development, Section on Growth and Development, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize assays of biomarkers midkine, pleiotrophin in biopsy samples for cancer detection. For collaboration opportunities, please contact Charlotte McGuinness at *mcguinnc@mail.nih.gov.*

Novel and Improved Methods for Constructing and Analyzing Synallele Libraries

Description of Technology: Methods of constructing and analyzing improved synallele libraries of nucleic acid molecules is disclosed. Each nucleic acid molecule in these libraries (i) comprises a different nucleic acid sequence and (ii) encodes a mammalian secreted protein comprising the same amino acid sequence. Synalleles are variants of a gene that have the same amino acid sequence but different DNA sequences. It has been shown that the redundancies in the genetic code can result in dramatically different protein expression levels. Currently available synallele libraries are too limited in their size, diversity, and fidelity to provide a clinical use (e.g., drug development). Also, one of the difficulties in producing therapeutic proteins is the lack of suitable methods for screening hundreds, or even thousands, of cells expressing such proteins in order to identify and isolate cells which express the desired proteins in high amounts. This invention provides the first synallele library assembled using type IIS restriction enzymes and comprises more than 100,000 individual clones. Several novel enhancements for constructing libraries with increased diversity of synalleles using segment shuffling techniques and synallele shuffling within segments using nicking and polymerization are also described. Additionally, the inventors also disclose an efficient cell sorting method using tethered beads to screen for clones producing/secreting high levels of target protein.

Potential Commercial Applications:

- Production of therapeutic proteins
- Screening of cells and clones for high expressors

Competitive Advantages: This technology provides for increased chances of finding a synallele for a biopharmaceutical protein that increases its expression, decreases the time it takes to make clinical grade material, and reduces its cost of production.

Development Stage:

- Early-stage
- Pre-clinical
- In vitro data available

Inventors: James L. Hartley and Andrew Waters (NCI)

Intellectual Property: HHS Reference Nos. E–218–2012/0, E–219–2012/0, E–220–2012/0, E–221–2012/0, and E–017–2013/0—US Application No. 61/725,807 filed 13 Nov 2012

Licensing Contact: Suryanarayana (Sury) Vepa, Ph.D., JD; 301–435–5020; *vepas@mail.nih.gov*

Super-Resolution Fluorescence Enhanced Imaging Using Bleaching/Blinking Assisted Localization Microscopy (BALM)

Description of Technology: The invention relates to systems and methods for localization microscopy for superresolution imaging of fluorescent molecules. The method utilizes intrinsic bleaching/blinking properties of fluorophores in which superresolution is achieved by capturing successive images and subtracting from each either the subsequent image. The location of a single fluorescent molecule can be identified when the molecules either photobleach, blink off, or blink between successive images using a higher magnification lens to achieve a smaller pixel size.

Potential Commercial Applications:

- Tissue imaging
- Cell structure imaging

Competitive Advantages: Higher magnification at lower pixel size

Development Stage:

- Prototype
- In vitro data available

Inventor: Bechara Kachar (NIDCD)

Publication: Burnette DT, et al. Bleaching/blinking assisted localization microscopy for superresolution imaging using standard fluorescent molecules. Proc Natl Acad Sci U S A. 2011 Dec 27;108(52):21081–6. [PMID 22167805]

Intellectual Property: HHS Reference No. E–247–2011/0—US Provisional Patent Application No. 61/784,266 filed 14 Mar 2013

Licensing Contact: Michael A. Shmilovich, Esq.; 301–435–5019; *shmilovm@mail.nih.gov*

Dated: June 6, 2013.

Richard U. Rodriguez,

Director, Division of Technology Development and Transfer, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2013–13895 Filed 6–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–13–008 Shared Instrumentation: Nuclear Magnetic Resonance.
Date: July 9–10, 2013.
Time: 11:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Nitsa Rosenzweig, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1102, MSC 7760, Bethesda, MD 20892, (301) 435–1747, *rosenzweign@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal Development, Injury and Regeneration.
Date: July 10–11, 2013.
Time: 9:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Rajiv Kumar, Ph.D., Chief, MOSS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4216, MSC 7802, Bethesda, MD 20892, 301–435–1212, *kumarra@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Child and Adolescent Psychopathology.
Date: July 10, 2013.
Time: 9:00 a.m. to 8:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Serena Chu, Ph.D., Scientific Review Officer, BBBP IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3178, MSC 7848, Bethesda, MD 20892, 301–500–5829, *sechu@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: Cell, Computational and Molecular Biology.
Date: July 10, 2013.
Time: 10:00 a.m. to 7:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).
Contact Person: Allen Richon, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6184, MSC 7892, Bethesda, MD 20892, 301–435–1024, *allen.richon@nih.hhs.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Diabetes and Obesity.
Date: July 10, 2013.
Time: 11:30 a.m. to 2:00 p.m.
Agenda: To review and evaluate grant applications.
Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).
Contact Person: Krish Krishnan, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6164, MSC 7892, Bethesda, MD 20892, (301) 435–1041, *krishnak@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 5, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–13891 Filed 6–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute Amended; Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board and NCI Board of Scientific Advisors, June 23, 2013, 05:00 p.m. to June 24, 2013, 5:15 p.m., National Institutes of Health, Building 31, C Wing, 6th Floor, 31 Center Drive, Conference Room 10, Bethesda, MD, 20892 which was published in the **Federal Register** on May 31, 2013, 78FR32672.

This notice is being amended to return the meeting to the original scheduled number of meeting days. The meeting is scheduled as followed: On June 23, 2013, open session from 5:00 p.m. to 8:15 p.m.; on June 24, 2013, open session from 9:00 a.m. to 5:00 p.m.; and on June 25, 2013, open session from 9:00 a.m. to 11:00 a.m. and a closed session from 11:00 a.m. to 12:00 p.m. The meeting is partially closed to the public.

Dated: June 6, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–13893 Filed 6–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–12–026: Functional Epigenomics: Developing Tools and Technologies for Manipulation of the Epigenome (R01).
Date: July 11–12, 2013.
Time: 8:00 a.m. to 4:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.
Contact Person: Raymond Jacobson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5858, MSC 7849, Bethesda, MD 20892, 301–996–7702, *jacobsonrh@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group; Behavioral and Social Science Approaches to Preventing HIV/AIDS Study Section.
Date: July 11–12, 2013.
Time: 8:00 a.m. to 5:00 p.m.
Agenda: To review and evaluate grant applications.
Place: Doubletree Hotel Washington, 1515 Rhode Island Ave. NW., Washington, DC 20005.
Contact Person: Jose H Guerrier, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of

Health, 6701 Rockledge Drive, Room 5222, MSC 7852, Bethesda, MD 20892, 301–435–1137, *guerriej@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; RFA–RM–12–022: Broadening Experiences in Scientific Training (DP7/BEST) Panel 1.

Date: July 11–12, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hyatt Regency Bethesda, One Bethesda Metro Center, 7400 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Lawrence E Boerboom, Ph.D., Chief, CVRS IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4130, MSC 7814, Bethesda, MD 20892, (301) 435–8367, *boerboom@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Genome Integrity and Tumor Progression.

Date: July 11, 2013.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Manzoor Zarger, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6208, MSC 7804, Bethesda, MD 20892, (301) 435–2477, *zargerma@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Molecular Neuropsychology.

Date: July 11, 2013.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov.*

Name of Committee: AIDS and Related Research Integrated Review Group; AIDS Molecular and Cellular Biology Study Section.

Date: July 12, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Mayflower Hotel, 1127 Connecticut Avenue NW., Washington, DC 20036.

Contact Person: Kenneth A Roebuck, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5214, MSC 7852, Bethesda, MD 20892, (301) 435–1166, *roebuckk@csr.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846– 93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: June 6, 2013.

Carolyn A. Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–13892 Filed 6–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of an Interagency Autism Coordinating Committee (IACC or Committee) meeting.

The purpose of the IACC meeting is to discuss committee business, updates and issues related to autism spectrum disorder (ASD) research and services activities. The meeting will be open to the public and will be accessible by webcast and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Open Meeting.

Date: July 9, 2013.

Time: 9:00 a.m. to 5:30 p.m.* Eastern Time

* Approximate end time.

Agenda: To discuss committee business, updates and issues related to ASD research and services activities.

Place: The National Institutes of Health, 31 Center Drive/Building 31, 6th Floor, C Wing, Conference Room 10, Bethesda, MD 20892.

Webcast Live: http://videocast.nih.gov/.

Conference Call Access: Dial: 800–369–3170, Access code: 9936478.

Cost: The meeting is free and open to the public.

Registration: Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis. To register, please visit: *https://pointpass.com/events/Interagency_Autism_Coordinating_Committee_July_9_2013/.*

Deadlines: Notification of intent to present oral comments: Friday, June 28, 2013 by 5:00 p.m. ET. Submission of written/electronic statement for oral comments: Tuesday, July 2, 2013 by 5:00 p.m. ET. Final Deadline for Submission of written comments: Tuesday, July 2, 2013 by 5:00 p.m. ET. Please note: The NIMH Office of Autism Research Coordination (OARC) anticipates that written public comments received by 5:00 p.m. ET, Friday, June 14, 2013 will be presented to the Committee prior to the July 9 meeting for the Committee's consideration. Any written comments received between June 14, 2013 and July 2, 2013 will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the staff time required to process them in accordance with privacy regulations and other applicable Federal policies.

Access: Medical Center Metro (Red Line).

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, National Institute of Mental Health, NIH, 6001 Executive Boulevard, Room 6182A, Bethesda, MD 20892–9669, Phone: 301–443–6040, Email: *IACCPublicInquiries@mail.nih.gov.*

Public Comments:

Any member of the public interested in presenting oral comments to the Committee must notify the Contact Person listed on this notice by 5:00 p.m. ET on Friday, June 28, 2013, with their request to present oral comments at the meeting. Interested individuals and representatives of organizations must submit a written/electronic copy of the oral presentation/statement including a brief description of the organization represented by 5:00 p.m. ET on Tuesday, July 2, 2013. Statements submitted will become a part of the public record. Only one representative of an organization will be allowed to present oral comments and presentations will be limited to three to five minutes per speaker, depending on number of speakers to be accommodated within the allotted time. Speakers will be assigned a time to speak in the order of the date and time when their request to speak is received, along with the required submission of the written/electronic statement by the specified deadline.

In addition, any interested person may submit written comments to the IACC prior to the meeting by sending the comments to the Contact Person listed on this notice by 5:00 p.m. ET on Tuesday, July 2, 2013. The comments should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. NIMH anticipates written public comments received by 5:00 p.m. ET, Friday, June 14, 2013 will be presented to the Committee prior to the meeting for the Committee's consideration. Any written comments received between June 14, 2013 and July 2, 2013 will be provided to the Committee either before or after the meeting, depending on the volume of comments received and the staff time required to process them in accordance with privacy regulations and other applicable Federal policies. All written public comments and oral public comment statements received by the deadlines for both oral and written public comments will be provided to the IACC for their consideration and will become part of the public record.

In the 2009 IACC Strategic Plan, the IACC listed the ''Spirit of Collaboration'' as one of its core values, stating that, ''We will treat others with respect, listen to diverse views with open minds, discuss submitted public comments, and foster discussions where participants can comfortably offer opposing opinions.'' In keeping with this core value, the IACC and the NIMH Office of Autism Research Coordination (OARC) ask that members of the public who provide public comments or participate in meetings of the IACC also seek to treat others with respect and consideration in their communications and actions, even when discussing issues of genuine concern or disagreement.

Remote Access:

The meeting will be open to the public through a conference call phone number and

webcast live on the Internet. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the webcast or conference call, please send an email to *helpdeskiacc@gmail.com* or by phone at 415–652–8023.

Individuals who participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 5 days prior to the meeting.

Security:

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit. Also as a part of security procedures, attendees should be prepared to present a photo ID at the meeting registration desk during the check-in process. Pre-registration is recommended. Seating will be limited to the room capacity and seats will be on a first come, first served basis, with expedited check-in for those who are pre-registered.

Meeting schedule subject to change.

Information about the IACC is available on the Web site: *http://www.iacc.hhs.gov.*

Dated: June 6, 2013.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2013–13894 Filed 6–11–13; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities; Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Registration for Behavioral Health Web site and Resources (OMB No. 0930–0313)—REVISION

The Substance Abuse and Mental Health Services Administration (SAMHSA) is requesting OMB approval for a revision to the Behavioral Health Web site and Resources data collection. SAMHSA is authorized under section 501(d)(16) of the Public Health Service Act (42 USC 290aa(d)(16)) to develop and distribute materials for the prevention, treatment, and recovery from substance abuse and mental health disorders. To improve customer service and lessen the burden on the public to locate and obtain these materials, SAMHSA has developed a Web site that includes more than 1,400 free publications from SAMHSA and its component Agencies: The Center for Substance Abuse Treatment, the Center for Substance Abuse Prevention, the Center for Mental Health Services, the Center for Behavioral Health Statistics and Quality, and other SAMHSA partners, such as the Office of National Drug Control Policy. These products are available to the public for ordering and download. When a member of the public chooses to order hard-copy publications, it is necessary for SAMHSA to collect certain customer information in order to fulfill the request. To further lessen the burden on the public and provide the level of customer service that the public has come to expect from product Web sites, SAMHSA has developed a voluntary registration process for its publication Web site that allows customers to create accounts. Through these accounts, SAMHSA customers are able to access their order histories and save their shipping addresses. This reduces the burden on customers of having to re-identify materials they ordered in the past and to re-enter their shipping information each time they place an order with SAMHSA. During the Web site registration process, SAMHSA also asks customers to provide optional demographic information that helps SAMHSA evaluate the use and distribution of its publications and improve services to the public.

SAMHSA is employing a Web-based form for information collection to avoid duplication and unnecessary burden on customers who register both for an account on the product Web site and for email updates. The Web technology allows SAMHSA to integrate the email update subscription process into the Web site account registration process. Customers who register for an account on the product Web site are given the option of being enrolled automatically to receive SAMHSA email updates. Any optional questions answered by the customer during the Web site registration process automatically are mapped to the profile generated for the email update system, thereby reducing the collection of duplicate information.

SAMHSA collects all customer information submitted for Web site registration and email update subscriptions electronically via a series of Web forms on the samhsa.gov domain. Customers can submit the Web forms at their leisure, or call SAMHSA's toll-free Call Center and an information specialist will submit the forms on their behalf. The electronic collection of information reduces the burden on the respondent and streamlines the data-capturing process. SAMHSA places Web site registration information into a Knowledge Management database and places email subscription information into a database maintained by a third-party vendor that serves multiple Federal agencies and the White House. Customers can change, add, or delete their information from either system at any time.

The respondents are behavioral health professionals, researchers, parents, caregivers, and the general public.

SAMHSA proposes two changes to the information collection. The first change is increasing the number of responses based on the average annual number of actual responses in 2011 and 2012. The second change is modifying the response options for ''Organization Type'' in the following ways: ''Treatment Facility'' will be changed to ''Behavioral Health Treatment Facility'', ''Individual/Group Practice'' will be changed to ''Other Health Care Facility'', and adding four new categories including ''Military/Veterans Organization,'' ''Criminal Justice/Courts,'' ''Health Insurer,'' and ''Human Resources/Employee Assistance Program.''

SAMHSA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Web Site Registration	38,605	1	38,605	.033 (2 min.)	1,286

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN—Continued

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Email Update Subscription	21,138	1	21,138	.017 (1 min.)	359
Total	59,743		59,743		1,645

Written comments and recommendations concerning the proposed information collection should be sent by July 12, 2013 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2013–13947 Filed 6–11–13; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Agency Information Collection Activities: Department of Homeland Security (DHS) Cybersecurity Education Office (CEO) National Initiative for Cybersecurity Careers and Studies (NICCS) Cybersecurity Training and Education Catalog (Training Catalog) Collection

AGENCY: Cybersecurity Education Office, DHS.

ACTION: 60-Day Notice and request for comments; New Collection (Request for a new OMB Control No.), 1601–NEW.

SUMMARY: The Department of Homeland Security, Cybersecurity Education Office, will submit the following Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35).

DATES: Comments are encouraged and will be accepted until August 12, 2013. This process is conducted in accordance with 5 CFR 1320.1

ADDRESSES: Written comments and questions about this Information Collection Request should be forwarded to Cybersecurity Education Office, DHS Attn.: Michael Wigal, *dhs.pra@hq.dhs.gov.*

SUPPLEMENTARY INFORMATION: Title II, Homeland Security Act, 6 U.S.C. 121(d)(1) To access, receive, and analyze law enforcement information, intelligence information and other information from agencies of the Federal Government, State and local government agencies* * *and Private sector entities and to integrate such information in support of the mission responsibilities of the Department. The following authorities also permit DHS to collect information of the type contemplated: Federal Information Security Management Act of 2002 (FISMA), 44 U.S.C. 3546; Homeland Security Presidential Directive (HSPD) 7, ''Critical Infrastructure Identification, Prioritization, and Protection'' (2003); and NSPD–54/HSPD–23, ''Cybersecurity Policy'' (2009).

In May 2009, the President ordered a Cyberspace Policy Review to develop a comprehensive approach to secure and defend America's infrastructure. The review built upon the Comprehensive National Cybersecurity Initiative (CNCI). In response to increased cyber threats across the Nation, the National Initiative for Cybersecurity Education (NICE) expanded from a previous effort, the CNCI #8. NICE formed in March 2011, and is a nationally coordinated effort comprised of over 20 federal departments and agencies, and numerous partners in academia and industry. NICE focuses on cybersecurity awareness, education, training and professional development. NICE seeks to encourage and build cybersecurity awareness and competency across the Nation and to develop an agile, highly skilled cybersecurity workforce.

The NICCS Portal is a national online resource for cybersecurity awareness, education, talent management, and professional development and training. NICCS Portal is an implementation tool for NICE. Its mission is to provide comprehensive cybersecurity resources to the public.

To promote cybersecurity education, and to provide a comprehensive resource for the Nation, NICE developed the Cybersecurity Training and Education Catalog. The Cybersecurity Training and Education Catalog will be hosted on the NICCS Portal. Both Training Course and Certification information will be stored in the Training Catalog. Note: Any information received from the public in support of the NICCS Portal and Cybersecurity Training and Education Catalog is completely voluntary. Organizations and individuals who do not provide information can still utilize the NICCS Portal and Cybersecurity Training and Education Catalog without restriction or penalty. An organization or individual who wants their information removed from the NICCS Portal and/or Cybersecurity Training and Education Catalog can email the NICCS Supervisory Office (SO).

Department of Homeland Security (DHS) Cybersecurity Education Office (CEO) intends for the collected information from the NICCS Cybersecurity Training Course Form and the NICCS Cybersecurity Certification Form to be displayed on a publicly accessible Web site called the National Initiative for Cybersecurity Careers and Studies (NICCS) Portal (*http://niccs.us-cert.gov/*). Collected information from the NICCS Cybersecurity Training Course Form and the NICCS Cybersecurity Certification Form will be included in the Cybersecurity Training and Education Catalog. Both sets of information will be made available to the public to support the National Initiative for Cybersecurity Education (NICE) mission and the Comprehensive National Cybersecurity Initiative (CNCI)—Initiative 8: Expand Cyber Education.

The DHS CEO NICCS Supervisory Office will use information collected from the NICCS Vetting Criteria Form to primarily manage communications with the training providers; this collected information will not be shared with the public and is intended for internal use only. Additionally, this information will

be used to validate training providers and certification owners before uploading their training course or certification information to the Training Catalog.

The information will be completely collected via electronic means. Collection will be exchanged between the public and DHS CEO via email (*niccs@hq.dhs.gov*). All information collected from the NICCS Cybersecurity Training Course Form and the follow-on NICCS Cybersecurity Training Course Web Form will be stored in the publicly accessible NICCS Cybersecurity Training and Education Catalog (*http://nics.us-cert.gov/training/training-home*). The NICCS Cybersecurity Certification Form and follow-on NICCS Cybersecurity Certification Web Form will also be stored in the publicly accessible NICCS Cybersecurity Training and Education Catalog (*http://nics.us-cert.gov/training/training-home*).

The NICCS SO will electronically store information collected via the NICCS Vetting Criteria Form. This information will not be publicly accessible. The Office of Management and Budget is particularly interested in comments which:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected; and
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Analysis

Agency: Cybersecurity Education Office, DHS.

Title: Department of Homeland Security (DHS) Cybersecurity Education Office (CEO). National Initiative for Cybersecurity Careers and Studies (NICCS) Cybersecurity. Training and Education Catalog (Training Catalog) Collection.

OMB Number: 1601–NEW.

Number of Respondents: 300.

Estimated Number of Responses: 2100.

Estimated Time per Respondent: 1 hour.

Total Burden Hours: 2100 hours.

Dated: June 4, 2013.

Margaret H. Graves,

Acting Chief Information Officer.

[FR Doc. 2013–13885 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–9B–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0017; OMB No. 1660–0086]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on an extension of a currently approved collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the National Flood Insurance Program, Mortgage Portfolio Protection Program (MPPP), which is an option that companies participating in the National Flood Insurance Program can use to bring their mortgage loan portfolios into compliance with the flood insurance purchase requirements.

DATES: Comments must be submitted on or before August 12, 2013.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2013–0017. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., Washington, DC 20472–3100.

(3) *Facsimile.* Submit comments to (703) 483–2999.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Susan Bernstein, Program Analyst; Mitigation Division, (202) 212–2113 for additional information. You may contact the Records Management Division for copies of the proposed collection of information at facsimile number (202) 646–3347 or email address: *FEMA-Information-Collections-Management@dhs.gov.*

SUPPLEMENTARY INFORMATION: The National Flood Insurance Program (NFIP) is authorized in Public Law 90–448 (1968) and expanded by Public Law 93–234 (1973), and is codified as 42 U.S.C. 4001, *et seq.* Public Law 103–325 (1994) expands upon this and provides federally supported flood insurance for existing buildings exposed to flood risk. In accordance with Public Law 93–234, the purchase of flood insurance is mandatory when federal or federally related financial assistance is being provided for acquisition in flood hazard areas of communities that are participating in the program. The Mortgage Portfolio Protection program (MPPP) is an option that companies participating in the NFIP can use to bring their mortgage loan portfolios into compliance with the flood insurance purchase requirements of the three public laws described above. 44 CFR 62.23(l)(1), with 44 CFR part 62, Appendix A implements the MPPP requirements for specific notices and other procedures be adhered. Insurance companies applying for or renewing their participation in the Write Your Own (WYO) program must indicate that they will adhere to the requirements of the MPPP if they are electing to voluntarily participate in the MPPP.

Collection of Information

Title: National Flood Insurance Program—Mortgage Portfolio Protection Program.

Type of Information Collection: Extension, without change, of a currently approved information collection.

FEMA Forms: None.

Abstract: FEMA needs the information to ensure that insurance companies that join the NFIP's WYO program meet all state and federal requirements for insurance companies; these include a good record and are well rated in their field. There is no other way to obtain this information which is

specific to each company that applies to join the NFIP.

Affected Public: Business or other non-profits.

Number of Respondents: 341.

Number of Responses: 341.

Estimated Total Annual Burden Hours: 171.

Estimated Cost: There are no record keeping, capital, start-up or maintenance costs associated with this information collections.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Dated: June 4, 2013.

Charlene D. Myrthil,

Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2013–13922 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–11–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2013–0019; OMB No. 1660–0026]

Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on an extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the State Administrative Plan for the procedural guide that details how the State will administer the HMGP.

DATES: Comments must be submitted on or before August 12, 2013.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *www.regulations.gov* under Docket ID FEMA–2013–0019. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Docket Manager, Office of Chief Counsel, DHS/FEMA, 500 C Street SW., Room 835, Washington, DC 20472–3100.

(3) *Facsimile.* Submit comments to (703) 483–2999.

(4) *Email.* Submit comments to *FEMA-POLICY@dhs.gov*. Include Docket ID FEMA–2013–0019 in the subject line.

All submissions received must include the agency name and Docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available via the link in the footer of *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Cecelia Rosenberg, Chief, Grants Policy Branch, Mitigation Division, at (202) 646–3321 for additional information. You may contact the Records Management Division for copies of the proposed collection of information at facsimile number (202) 646–3347 or email address: *FEMA-Information-Collections-Management@dhs.gov*.

SUPPLEMENTARY INFORMATION: FEMA regulations in 44 CFR 206.437 require development and update of the State Administrative Plan by State Grantees as a condition of receiving Hazard Mitigation Grant Program (HMGP) funding under section 404 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act of 1988, 42 U.S.C. 5170c. Grantees can be any State of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands, or an Indian tribal government that chooses to act as a grantee. A State is defined in 44 CFR part 13 as any of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments. Section 404 mandates FEMA approval of the State Administrative Plan before awarding any project grant assistance to a community or State applicant.

Collection of Information

Title: State Administrative Plan for the Hazard Mitigation Grant Program.

Type of Information Collection: Extension, without change, of a currently approved information collection.

FEMA Forms: None.

Abstract: The State Administrative Plan is a procedural guide that details how the State will administer the HMGP. The State must have a current administrative plan approved by the appropriate FEMA Regional Administrator before receiving HMGP funds. The administrative plan may take any form including a chapter within a comprehensive State mitigation program strategy.

Affected Public: State, local or Tribal government.

Number of Respondents: 32.

Number of Responses: 64.

Estimated Total Annual Burden Hours: 512.

Estimated Cost: There are no record keeping, capital, start-up or maintenance costs associated with this information collection.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) Evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Dated: June 4, 2013.

Charlene D. Myrthil,

Director, Records Management Division, Mission Support Bureau, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2013–13919 Filed 6–11–13; 8:45 am]

BILLING CODE 9111–13–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–3362–EM; Docket ID FEMA–2013–0001]

Massachusetts; Amendment No. 1 to Notice of an Emergency Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of an emergency declaration for the Commonwealth of Massachusetts (FEMA–3362–EM), dated April 17, 2013, and related determinations.

DATES: *Effective Date:* June 5, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of an emergency declaration for the Commonwealth of Massachusetts is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared an emergency by the President in his declaration of April 17, 2013.

Bristol County for emergency protective measures (Category B), including direct federal assistance, under the Public Assistance program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–13933 Filed 6–11–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: New or modified Base (1% annual-chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or the regulatory floodway (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard determinations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

These new or modified flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

These new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Arkansas:					
Saline (FEMA Docket No.: B–1305).	City of Benton (12–06–0842P).	The Honorable Dave Mattingly, Mayor, City of Benton, P.O. Box 607, Benton, AR 72018.	114 South East Street, Benton, AR 72015.	April 22, 2013	050192
Saline (FEMA Docket No.: B–1305).	City of Bryant (12–06–0842P).	The Honorable Jill Dabbs, Mayor, City of Bryant, 210 Southwest 3rd Street, Bryant, AR 72022.	210 Southwest 3rd Street, Bryant, AR 72022.	April 22, 2013	050308
Saline (FEMA Docket No.: B–1305).	Unincorporated areas of Saline County (12–06–0842P).	The Honorable Lanny Fite, Saline County Judge, Saline County Courthouse, 200 North Main Street, Room 117, Benton, AR 72015.	Saline County Courthouse, 200 North Main Street, Room 117, Benton, AR 72015.	April 22, 2013	050191
New Mexico:					
Sandoval (FEMA Docket No.: B–1291).	Village of Corrales (12–06–1884P).	The Honorable Phillip Gasteyer, Mayor, Village of Corrales, 4324 Corrales Road, Corrales, NM 87048.	Village Hall, 4324 Corrales Road, Corrales, NM 87048..	April 1, 2013	350094
Oklahoma:					
Tulsa (FEMA Docket No.: B–1297).	City of Jenks (12–06–3225P).	Mr. Mike Tinker, Manager, City of Jenks, P.O. Box 2007, Jenks, OK 74037.	211 North Elm Street Jenks, OK 74037.	April 12, 2013	400209
Pennsylvania:					
Chester (FEMA Docket No.: B–1291).	Township of West Goshen (12–03–1877P).	The Honorable Raymond H. Halvorsen, Chairman, Township of West Goshen, Board of Supervisors, 1025 Paoli Pike, West Chester, PA 19380.	West Goshen Township Building, 1025 Paoli Pike, West Chester, PA 19380.	April 4, 2013	420293
Texas:					
Bell (FEMA Docket No.: B–1305).	City of Killeen (12–06–0554P).	The Honorable Daniel A. Corbin, Mayor, City of Killeen, P.O. Box 1329, Killeen, TX 76541.	City Hall, 101 North College Street, Killeen, TX 76540.	April 22, 2013	480031
Collin (FEMA Docket No.: B–1305).	City of Plano (12–06–0656P).	The Honorable Phil Dyer, Mayor, City of Plano, 1520 Avenue K, Plano, TX 75074.	City Hall, 1520 Avenue K, Plano, TX 75074.	April 26, 2013	480140
Harris (FEMA Docket No.:B–1291).	Unincorporated areas of Harris County (12–06–3202P).	The Honorable Ed Emmett, Harris County Judge, 1001 Preston, Suite 911, Houston, TX 77002.	Harris County, 10555 Northwest Freeway, Houston, TX 77092.	April 11, 2013	480287
Lamar (FEMA Docket No.: B–1291).	Unincorporated areas of Lamar County (12–06–2815P).	The Honorable Chuck Superville, Jr., Lamar County Judge, 119 North Main Street, Paris, TX 75460.	Lamar County Courthouse, 119 North Main Street, Paris, TX 75460.	April 1, 2013	480891
Lubbock (FEMA Docket No.: B–1279).	City of Lubbock (12–06–1157P).	The Honorable Glen Robertson, Mayor, City of Lubbock, P.O. Box 2000, Lubbock, TX 79457.	City Hall, 1625 13th Street, Lubbock, TX 79401.	January 22, 2013	480452
Virginia:					
City of Bristol (FEMA Docket No.: B–1291).	City of Bristol (12–03–0985P).	Mr. Dewey P. Cashwell, Jr., Manager, City of Bristol, 300 Lee Street, Bristol, VA 24201.	Virginia City Hall, 300 Lee Street, Bristol, VA 24201.	April 11, 2013	510022
City of Virginia Beach (FEMA Docket No.: B–1297).	City of Virginia Beach (12–03–2078P).	The Honorable William D. Sessoms, Jr., Mayor, City of Virginia Beach, City Hall, Building 1, 2401 Courthouse Drive, Virginia Beach, VA 23456.	Department of Public Works, Municipal Center, Building 2, 2405 Courthouse Drive, Virginia Beach, VA 23456.	April 11, 2013	515531
Stafford (FEMA Docket No.: B–1291).	Unincorporated areas of Stafford County (12–03–0748P).	The Honorable Susan Stimpson, Chairman, Stafford County Board of Supervisors, 1300 Courthouse Road, Stafford, VA 22554.	Stafford County Administration Center, 1300 Courthouse Road, Stafford, VA 22554.	April 1, 2013	510154

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: May 17, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–13938 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002; Internal Agency Docket No. FEMA–B–1327]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR Part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR Part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
California:						
Santa Barbara	City of Lompoc, (13–09–0272P).	The Honorable John Linn, Mayor, City of Lompoc, 100 Civic Center Plaza, Lompoc, CA 93436.	100 Civic Center Plaza, Lompoc, CA 93436.	*http://www.r9map.org/Docs/13–09–0272P–060334–102IAC.pdf.*	July 31, 2013	060334
Idaho:						
Ada	Unincorporated areas of Ada County, (13–10–0375P).	The Honorable Dave Case, Chairman, Ada County Board of Commissioners, 200 West Front Street, 3rd Floor, Boise, ID 83702.	200 West Front Street, Boise, ID 83702.	*http://www.starr-team.com/starr/LOMR/Pages/RegionX.aspx.*	August 15, 2013	160001
Blaine	Unincorporated areas of Blaine County, (13–10–0554P).	The Honorable Angenie McCleary, Chairman, Blaine County Board of Commissioners, 206 1st Avenue South, Suite 300, Hailey, ID 83333.	Blaine County Planning and Zoning, 219 1st Avenue South, Suite 208, Hailey, ID 83333.	*http://www.starr-team.com/starr/LOMR/Pages/RegionX.aspx.*	August 15, 2013	165167
Illinois:						

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Peoria	City of Peoria, (12–05–5395P).	The Honorable Jim Ardis, Mayor, City of Peoria, 419 Fulton Street, Room 207, Peoria, IL 61602.	Peoria City Hall, Public Works Department, 419 Fulton Street, Room 307, Peoria, IL 61602.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	August 9, 2013	170536
McLean	Town of Normal, (11–05–4448P).	The Honorable Chris C. Koos, Mayor, Town of Normal, 100 East Phoenix Avenue, Normal, IL 61761.	City of Public Works Department, 211 South Linden Street, Normal, IL 61761.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	August 16, 2013	170502
Dupage	Village of Glen Ellyn, (13–05–2368P).	The Honorable Mark Pfefferman, Village President, Village of Glen Ellyn, 535 Duane Street, Glen Ellyn, IL 60137.	Village Hall, 535 Duane Street, Glen Ellyn, IL 60137.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	August 2, 2013	170207
Will	Village of Romeoville, (12–05–1759P).	The Honorable John D. Noak, Mayor, Village of Romeoville, 1050 West Romeo Road, Romeoville, IL 60446.	Village Hall, 1050 West Romeo Road, Romeoville, IL 60446.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	July 19, 2013	170711
Will	Unincorporated areas of Will County, (12–05–1759P).	The Honorable Lawrence M. Walsh, County Executive, Will County, 302 North Chicago Street, Joliet, IL 60432.	Will County Land Use, 58 East Clinton Street, Suite 500, Joliet, IL 60432.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	July 19, 2013	170695
Kansas:						
Sedgwick	Unincorporated areas of Sedgwick County, (12–07–0465P).	The Honorable Tim R. Norton, Chairman, Sedgwick County Board of Commissioners, 525 North Main Street, Suite 320, Wichita, KS 67203.	144 South Seneca Street, Wichita, KS 67213.	*http://www.starr-team.com/starr/LOMR/Pages/RegionVII.aspx.*	March 12, 2013	200321
Sedgwick	City of Wichita, (12–07–0465P).	The Honorable Carl Brewer, Mayor, City of Wichita, 455 North Main Street, Wichita, KS 67202.	455 North Main Street, 8th Floor, Wichita, KS 67202.	*http://www.starr-team.com/starr/LOMR/Pages/RegionVII.aspx.*	March 12, 2013	200328
Sedgwick	City of Maize, (12–07–0465P).	The Honorable Clair Donnelly, Mayor, City of Maize, 10100 West Grady Avenue, Maize, KS 67101.	10100 West Grady Avenue, Maize, KS 67101.	*http://www.starr-team.com/starr/LOMR/Pages/RegionVII.aspx.*	March 12, 2013	200520
Michigan:						
Macomb	Township of Macomb, (12–05–7428P).	The Honorable Janet I. Dunn, Supervisor, Macomb Township, 54111 Broughton Road, Macomb, MI 48042.	54111 Broughton Road, Macomb, MI 48042.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	August 16, 2013	260445
Nebraska:						
Colfax	Village of Leigh, (12–07–2322P).	The Honorable Larry Fuhr, Chairman, Leigh Village Board, P.O. Box 277, Leigh, NE 68643.	109 Short Street, Leigh, NE 68643.	*http://www.starr-team.com/starr/LOMR/Pages/RegionVII.aspx.*	July 25, 2013	310386
Colfax	Unincorporated areas of Colfax County, (12–07–2322P).	The Honorable Jerry Heard, Chairman, Colfax County Board of Commissioners, P.O. Box 435, Schuyler, NE 68641.	411 East 11 th Street, Schuyler, NE 68661.	*http://www.starr-team.com/starr/LOMR/Pages/RegionVII.aspx.*	July 25, 2013	310426
Platte	Unincorporated areas of Platte County, (12–07–2322P).	The Honorable Jerry Micek, Chairman, Platte County Board of Commissioners, 2610 14th Avenue, Columbus, NE 68601.	2610 14 th Street, Columbus, NE 68601.	*http://www.starr-team.com/starr/LOMR/Pages/RegionVII.aspx.*	July 25, 2013	310467
Minnesota:						
Steele	City of Owatonna, (12–05–7769P).	The Honorable Thomas A. Kuntz, Mayor, City of Owatonna, 540 West Hills Circle, Owatonna, MN 55060.	540 West Hills Circle, Owatonna, MN 55060.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	July 26, 2013	270463
Olmsted	City of Rochester, (13–05–0422P).	The Honorable Ardell F. Brede, Mayor, City of Rochester, 201 4th Street Southeast, Room 281, Rochester, MN 55904.	2122 Campus Drive Southeast, Suite 100, Rochester, MN 55904.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	July 26, 2013	275246

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Olmsted	Unincorporated areas of Olmsted County, (13–05–0422P).	The Honorable Jim Bier, Chairperson, Olmsted County Board of Commissioners, 151 4th Street Southeast, Rochester, MN 55904.	2122 Campus Drive Southeast, Suite 100, Rochester, MN 55904.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	July 26, 2013	270626
Missouri:						
Pulaski	Unincorporated areas of Pulaski County, (13–07–0592P).	The Honorable Gene Newkirk, Presiding Commissioner, Pulaski County, 301 Historic 66 East, Suite 101, Waynesville, MO 65583.	301 Historic 66 East, Suite 101, Waynesville, MO 65583.	*http://www.starr-team.com/starr/LOMR/Pages/RegionVII.aspx.*	July 22, 2013	290826
Wisconsin:						
Chippewa	City of Bloomer, (13–05–0677P).	The Honorable Randy Summerfield, Mayor, City of Bloomer, 1503 Main Street, Bloomer, WI 54724.	1503 Main Street, Bloomer, WI 54724.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	August 14, 2013	550042
Chippewa	Unincorporated areas of Chippewa County, (13–05–0677P).	The Honorable Paul Michels, Chairman, Chippewa County Board of Supervisors, 711 North Bridge Street, Chippewa Falls, WI 54729.	711 North Bridge Street Room 9, Chippewa Falls, WI 54729.	*http://www.starr-team.com/starr/LOMR/Pages/RegionV.aspx.*	August 14, 2013	555549
Wyoming:						
Fremont	Town of Dubois, (13–08–0063P).	The Honorable Twila Blakeman, Mayor, Town of Dubois, 712 Meckem Street, Dubois, WY 82513.	712 Meckem Street, Dubois, WY 82513.	*http://www.bakeraecom.com/index.php/wyoming/fremont-2.*	August 9, 2013	560018
Fremont	Unincorporated areas of Fremont County, (13–08–0063P).	The Honorable Douglas L. Thompson, Chairman, Fremont County Board of Commissioners, 450 North 2nd Street, Lander, WY 82520.	450 North 2nd Street, Room 360, Lander, WY 82520.	*http://www.bakeraecom.com/index.php/wyoming/fremont-2.*	August 9, 2013	560080

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: May 17, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–13940 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: New or modified Base (1% annual-chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or the regulatory floodway (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard determinations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

These new or modified flood hazard determinations, together with the

floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

These new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Alabama:					
Jefferson (FEMA Docket No.: B–1294).	City of Birmingham (12–04–6207P).	The Honorable William A. Bell, Mayor, City of Birmingham, 710 North 20th Street, 3rd Floor, Birmingham, AL 35203.	City Hall, 710 North 20th Street, 3rd Floor, Birmingham, AL 35203.	April 5, 2013	010116
Mobile (FEMA Docket No.: B–1298).	City of Prichard (12–04–4608P).	The Honorable Ron Davis, Mayor, City of Prichard, 216 East Prichard Avenue, Prichard, AL 36610.	City Hall, 216 East Prichard Avenue, Prichard, AL 36610.	April 29, 2013	010170
Shelby (FEMA Docket No.: B–1294).	City of Montevallo (12–04–7810P).	The Honorable Ben McCrory, Mayor, City of Montevallo, 545 Main Street, Montevallo, AL 35115.	City Hall, 545 Main Street, Montevallo, AL 35115.	April 4, 2013	010349
Shelby (FEMA Docket No.: B–1294).	City of Pelham (12–04–7869P).	The Honorable Don Murphy, Mayor, City of Pelham, 3162 Pelham Parkway, Pelham, AL 35124.	City Hall, 3162 Pelham Parkway, Pelham, AL 35124.	April 11, 2013	010193
Shelby (FEMA Docket No.: B–1294).	Town of Indian Springs Village (12–04–7869P).	The Honorable Steve Zerkis, Mayor, Town of Indian Springs Village, 5300 Mountain Park Drive, Indian Springs, AL 35124.	Town Hall 5300 Mountain Park Drive, Indian Springs, AL 35124.	April 11, 2013	010430
Shelby (FEMA Docket No.: B–1294).	Unincorporated areas of Shelby County (12–04–7869P).	The Honorable Lindsey Allen, Chairman, Shelby County Board of Supervisors, 200 West College Street, Columbiana, AL 35051.	Shelby County Engineer's Office 506 Highway, 70 Columbiana, AL 35051.	April 11, 2013	010191
Tuscaloosa (FEMA Docket No.: B–1294).	City of Tuscaloosa (12–04–3302P).	The Honorable Walter Maddox, Mayor, City of Tuscaloosa, 2201 University Boulevard, Tuscaloosa, AL 35401.	Engineering Department, 2201 University Boulevard, Tuscaloosa, AL 35401.	April 22, 2013	010203
Tuscaloosa (FEMA Docket No.: B–1294).	City of Tuscaloosa (12–04–3303P).	The Honorable Walter Maddox, Mayor, City of Tuscaloosa, 2201 University Boulevard, Tuscaloosa, AL 35401.	Engineering Department, 2201 University Boulevard, Tuscaloosa, AL 35401.	April 22, 2013	010203
Arizona:					
Maricopa (FEMA Docket No.: B–1294).	City of Phoenix (13–09–0280P).	The Honorable Greg Stanton, Mayor, City of Phoenix, 200 West Washington Street, 11th Floor, Phoenix, AZ 85003.	Street Transportation Department, 200 West Washington Street, 5th Floor, Phoenix, AZ 85003.	April 8, 2013	040051
California:					
Santa Clara (FEMA Docket No.: B–1294).	City of Cupertino (12–09–2521P).	The Honorable Mark Santoro, Mayor, City of Cupertino, 10300 Torre Avenue, Cupertino, CA 95014.	Planning Department, 10300 Torre Avenue, Cupertino, CA 95014.	April 4, 2013	060339
Santa Clara (FEMA Docket No.: B–1294).	City of Los Altos (12–09–2859P).	The Honorable Val Carpenter, Mayor, City of Los Altos, 1 North San Antonio Road, Los Altos, CA 94022.	Public Works Department, 1 North San Antonio Road, Los Altos, CA 94022.	April 18, 2013	060341
Santa Clara (FEMA Docket No.: B–1294).	City of San Jose (12–09–2521P).	The Honorable Chuck Reed, Mayor, City of San Jose, 200 East Santa Clara Street, San Jose, CA 95113.	Department of Public Works, 200 East Santa Clara Street Tower, 3rd Floor, San Jose, CA 95113.	April 4, 2013	060349
Santa Clara (FEMA Docket No.: B–1294).	City of Saratoga (12–09–2521P).	The Honorable Chuck Page, Mayor, City of Saratoga, 13777 Fruitvale Avenue, Saratoga, CA 95070.	Planning Department, 13777 Fruitvale Avenue, Saratoga, CA 95070.	April 4, 2013	060351
Santa Clara (FEMA Docket No.: B–1294).	Town of Los Altos Hills (12–09–2859P).	The Honorable Rich Larsen, Mayor, Town of Los Altos Hills, 26379 Fremont Road, Los Altos Hills, CA 94022.	Public Works Department, 26379 Fremont Road, Los Altos Hills, CA 94022.	April 18, 2013	060342
Colorado:					
Adams (FEMA Docket No.: B–1294).	City of Thornton (12–08–0595P).	The Honorable Heidi Williams, Mayor, City of Thornton, 9500 Civic Center Drive, Thornton, CO 80229.	9500 Civic Center Drive, Thornton, CO 80229.	April 12, 2013	080007

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Adams (FEMA Docket No.: B–1294).	Unincorporated areas of Adams County (12–08–0595P).	The Honorable W. R. "Skip" Fischer, Chairman, Adams County Board of Commissioners, 4430 South Adams County Parkway, 5th Floor, Suite C5000A, Brighton, CO 80601.	Adams County Public Works Department, 4430 South Adams County Parkway, 1st Floor, Suite W2123, Brighton, CO 80601.	April 12, 2013	080001
Arapahoe (FEMA Docket No.: B–1294).	City of Centennial (12–08–0553P).	The Honorable Cathy Noon, Mayor, City of Centennial, 13133 East Arapahoe Road, Centennial, CO 80112.	Southeast Metro Stormwater Authority, 76 Inverness Drive East, Suite A, Centennial, CO 80112.	April 12, 2013	080315
Weld (FEMA Docket No.: B–1298).	Town of Frederick (12–08–0198P).	The Honorable Tony Carey, Mayor, Town of Frederick, P.O. Box 435, Frederick, CO 80530.	Planning Department, 401 Locust Street, Frederick, CO 80530.	April 15, 2013	080244
Weld (FEMA Docket No.: B–1298).	Unincorporated areas of Weld County (12–08–0198P).	The Honorable Sean Conway, Chairman, Weld County Board of Commissioners, P.O. Box 758, Greeley, CO 80632.	Weld County Public Works Department, 1111 H Street, Greeley, CO 80632.	April 15, 2013	080266
Florida:					
Broward (FEMA Docket No.: B–1298).	Town of Hollywood (12–04–8174P).	The Honorable Peter J. M. Bober, Mayor, City of Hollywood, P.O. Box 229045, Hollywood, FL 33022.	City Hall, 2600 Hollywood Boulevard, Hollywood, FL 33020.	April 26, 2013	125113
Collier (FEMA Docket No.: B–1298).	City of Naples (12–04–5497P).	The Honorable John F. Sorey, III, Mayor, City of Naples, 735 8th Street, South Naples, FL 34102.	Building Department, 295 Riverside Circle, Naples, FL 34102.	April 19, 2013	125130
Leon (FEMA Docket No.: B–1294).	Unincorporated areas of Leon County (12–04–6893P).	The Honorable Nicholas J. Maddox, Chairman, Leon County Board of Commissioners, 301 South Monroe Street, 5th Floor Tallahassee, FL 32301.	Leon County Courthouse, 301 South Monroe Street, Tallahassee, FL 32301.	April 19, 2013	120143
Miami-Dade (FEMA Docket No.: B–1294).	City of Sunny Isles Beach (12–04–6538P).	The Honorable Norman S. Edelcup, Mayor, City of Sunny Isles Beach, 18070 Collins Avenue, Sunny Isles Beach, FL 33160.	City Hall, 18070 Collins Avenue, Sunny Isles Beach, FL 33160.	April 8, 2013	120688
Orange (FEMA Docket No.: B–1294).	City of Orlando (12–04–4611P).	The Honorable Buddy Dyer, Mayor, City of Orlando, P.O. Box 4990, Orlando, FL 32808.	Permitting Services Department, 400 South Orange Avenue, Orlando, FL 32801.	April 19, 2013	120186
Orange (FEMA Docket No.: B–1314).	City of Orlando (12–04–6931P).	The Honorable Buddy Dyer, Mayor, City of Orlando, P.O. Box 4990, Orlando, FL 32808.	One City Commons, 400 South Orange Avenue, Orlando, FL 32808.	March 8, 2013	120186
Orange (FEMA Docket No.: B–1294).	Unincorporated areas of Orange County (12–04–4611P).	The Honorable Teresa Jacobs, Mayor, Orange County, 201 South Rosalind Avenue, Orlando, FL 32801.	Orange County Stormwater Management Department, 4200 South John Young Parkway, Orlando, FL 32839.	April 19, 2013	120179
Santa Rosa (FEMA Docket No.: B–1308).	Unincorporated areas of Santa Rosa County (13–04–0043P).	The Honorable Jim Williamson, Chairman, Santa Rosa County Board of Commissioners, 6495 Carolina Street, Suite M, Milton, FL 32570.	Santa Rosa County Development Services Department, 6051 Old Bagdad Highway, Room 202, Milton, FL 32583.	April 4, 2013	120274
Walton (FEMA Docket No.: B–1294).	Unincorporated areas of Walton County (12–04–6405P).	The Honorable Scott Brannon, Chairman, Walton County Commissioners, 415 Highway 20, Freeport, FL 32439.	Walton County Courthouse Annex, 47 North 6th Street, DeFuniak Springs, FL 32435.	April 5, 2013	120317
Kentucky:					
Fayette (FEMA Docket No.: B–1298).	Lexington-Fayette Urban County Government (12–04–4610P).	The Honorable James P. Gray, II, Mayor, Lexington-Fayette Urban County Government, 200 East Main Street, Lexington, KY 40507.	Lexington-Fayette Urban County Government Center, 200 East Main Street, Lexington, KY 40507.	April 8, 2013	210067
Nevada:					
Clark (FEMA Docket No.: B–1298).	Unincorporated areas of Clark County (13–09–0072P).	The Honorable Susan Brager, Chair, Clark County Board of Commissioners, 500 South Grand Central Parkway, Las Vegas, NV 89155.	Public Works Department, 500 South Grand Central Parkway, Las Vegas, NV 89155.	April 1, 2013	320003
South Carolina:					
Richland (FEMA Docket No.: B–1308).	City of Columbia (11–04–8071P).	The Honorable Steve Benjamin, Mayor, City of Columbia, 1737 Main Street, Columbia, SC 29201.	City Hall, 1737 Main Street, Columbia, SC 29021.	April 29, 2013	450172
Tennessee:					

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Shelby (FEMA Docket No.: B–1294).	City of Germantown (12–04–5413P).	The Honorable Sharon Goldsworthy, Mayor, City of Germantown, 1930 South Germantown Road, Germantown, TN 38138.	Economic and Community Development Department, 1920 South Germantown Road, Germantown, TN 38138.	April 12, 2013	470353
Wyoming:					
Laramie (FEMA Docket No.: B–1294).	Unincorporated areas of Laramie County (12–08–0028P).	The Honorable Gay Woodhouse, Chair, Laramie County Board of Commissioners, P.O. Box 1888, Cheyenne, WY 82001.	Laramie County Planning Department, Historic County Courthouse, 310 West 19th Street, Suite 400, Cheyenne, WY 82001.	April 8, 2013	560029

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: May 17, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–13926 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002; Internal Agency Docket No. FEMA–B–1324]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR Part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR Part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of Letter of Map Revision	Effective date of modification	Community No.
New Mexico:						
Bernalillo	City of Albuquerque, (12–06–3488P).	The Honorable Richard J. Berry, Mayor, City of Albuquerque, P.O. Box 1293, Albuquerque, NM 87103.	Development and Building Services Division, 600 2nd Street Northwest, Suite 201, Albuquerque, NM 87102.	*http://www.rampp-team.com/lomrs.htm.*	August 12, 2013	350002
Oklahoma:						
Oklahoma	City of Oklahoma City,. (12–06–4147P)	The Honorable Mick Cornett, Mayor, City of Oklahoma City, 200 North Walker Avenue, 3rd Floor, Oklahoma City, OK 73102.	420 West Main Street, Suite 700, Oklahoma City, OK 73102.	*http://www.rampp-team.com/lomrs.htm.*	August 12, 2013	405378
Woods	Unincorporated areas of Woods County, (12–06–2877P).	The Honorable Clint Strawn, Chairman, Woods County Board of Commissioners, P.O. Box 386, Alva, OK 73717.	Woods County Courthouse, 407 Government Street, Alva, OK 73717.	*http://www.rampp-team.com/lomrs.htm.*	August 12, 2013	400481
Texas:						
Brazos	City of Bryan, (12–06–2987P).	The Honorable Jason Bienski, Mayor, City of Bryan, 300 South Texas Avenue, Bryan, TX 77803.	City Hall, 300 South Texas Avenue, Bryan, TX 77803.	*http://www.rampp-team.com/lomrs.htm.*	August 12, 2013	480082
Denton	City of Frisco, (12–06–4054P).	The Honorable Maher Maso, Mayor, City of Frisco, 6101 Frisco Square Boulevard, Frisco, TX 75034.	City Hall, 6101 Frisco Square Boulevard, Frisco, TX 75034.	*http://www.rampp-team.com/lomrs.htm.*	August 19, 2013	480134
Denton	Town of Little Elm, (12–06–4054P).	The Honorable David Hillock, Mayor, Town of West Elm, 100 West Eldorado Parkway, Little Elm, TX 75068.	Town Hall, 100 West Eldorado Parkway, Little Elm, TX 75068.	*http://www.rampp-team.com/lomrs.htm.*	August 19, 2013	481152
Fort Bend	City of Katy, (12–06–1798P).	The Honorable Don Elder, Jr., Mayor, City of Katy, P.O. Box 617, Katy, TX 77493.	Public Works Department, 910 Avenue C, Katy, TX 77493.	*http://www.rampp-team.com/lomrs.htm.*	August 2, 2013	480301
Hays	City of Niederwald, (12–06–3911P).	The Honorable Reynell Smith, Mayor, City of Niederwald, 13851 Camino Real, Niederwald, TX 78640.	City Office, 13851 Camino Real, Niederwald, TX 78640.	*http://www.rampp-team.com/lomrs.htm.*	August 15, 2013	481670
Hays	Unincorporated areas of Hays County, (12–06–3911P).	The Honorable Bert Cobb, M.D., Hays County Judge, 111 East San Antonio Street, Suite 300, San Marcos, TX 78666.	Hays County Environmental Health Department, 1251 Civic Center Loop, San Marcos, TX 78666.	*http://www.rampp-team.com/lomrs.htm.*	August 15, 2013	480321
Tarrant	City of Fort Worth, (12–06–1459P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, 1000 Throckmorton Street, Fort Worth, TX 76102.	*http://www.rampp-team.com/lomrs.htm.*	May 20, 2013	480596
Tarrant	City of Fort Worth, (12–06–3084P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, 1000 Throckmorton Street, Fort Worth, TX 76102.	*http://www.rampp-team.com/lomrs.htm.*	July 11, 2013	480596
Tarrant	City of Westworth Village, (12–06–1459P).	The Honorable Tony Yeager, Mayor, City of Westworth Village, 311 Burton Hill Road, Westworth Village, TX 76114.	City Hall, 311 Burton Hall Road, Westworth Village, TX 76114.	*http://www.rampp-team.com/lomrs.htm.*	May 20, 2013	480616
Travis	City of Austin, (13–06–0132P).	The Honorable Lee Leffingwell, Mayor, City of Austin, P.O. Box 1088, Austin, TX 78767.	Stormwater Management Division, 505 Barton Springs Road, Suite 908, Austin, TX 78704.	*http://www.rampp-team.com/lomrs.htm.*	August 8, 2013	480624
West Virginia:						
Kanawha	Unincorporated areas of Kanawha County, (13–03–0645P).	The Honorable W. Kent Carper, President, Kanawha County Commission, 407 Virginia Street East, Charleston, WV 25301.	Kanawha County Courthouse, Planning and Development Department, 407 Virginia Street East, Charleston, WV 25301.	*http://www.rampp-team.com/lomrs.htm.*	August 12, 2013	540070

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: May 17, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–13934 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2013–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: New or modified Base (1% annual-chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or the regulatory floodway (hereinafter referred to as flood hazard determinations) as shown on the indicated Letter of Map Revision (LOMR) for each of the communities listed in the table below are finalized. Each LOMR revises the Flood Insurance Rate Maps (FIRMs), and in some cases the Flood Insurance Study (FIS) reports, currently in effect for the listed communities. The flood hazard determinations modified by each LOMR will be used to calculate flood insurance premium rates for new buildings and their contents.

DATES: The effective date for each LOMR is indicated in the table below.

ADDRESSES: Each LOMR is available for inspection at both the respective Community Map Repository address listed in the table below and online through the FEMA Map Service Center at *www.msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*; or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final flood hazard determinations as shown in the LOMRs for each community listed in the table below. Notice of these modified flood hazard determinations has been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

The modified flood hazard determinations are made pursuant to section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The new or modified flood hazard determinations are the basis for the floodplain management measures that the community is required either to adopt or to show evidence of being already in effect in order to remain qualified for participation in the National Flood Insurance Program (NFIP).

These new or modified flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities.

These new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and also are used to calculate the appropriate flood insurance premium rates for new buildings, and for the contents in those buildings. The changes in flood hazard determinations are in accordance with 44 CFR 65.4.

Interested lessees and owners of real property are encouraged to review the final flood hazard information available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Arizona:					
Maricopa (FEMA Docket No.: B–1306).	Unincorporated areas of Maricopa County (12–09–2950P).	The Honorable Max W. Wilson Chairman, Maricopa County Board of Supervisors, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Maricopa County Flood Control District, 2801 West Durango Street, Phoenix, AZ 85009.	April 5, 2013	040037
California:					
San Bernardino (FEMA Docket No.: B–1306).	City of Fontana (12–09–2642P).	The Honorable Acquanetta Warren, Mayor, City of Fontana, 8353 Sierra Avenue, Fontana, CA 92335.	Fontana City Hall, 8353 Sierra Avenue, Fontana, CA 92335.	May 13, 2013	060274
Illinois:					
DuPage (FEMA Docket No.: B–1306).	City of Darien (13–05–1709P).	The Honorable Kathleen A. Weaver, Mayor, City of Darien, 1702 Plainfield Road, Darien, IL 60561.	Darien City Hall, 1702 Plainfield Road, Darien, IL 60561.	May 28, 2013	170750
Peoria (FEMA Docket No.: B–1306).	City of Peoria (12–05–7861P).	The Honorable Jim Ardis Mayor, City of Peoria, 6141 North Evergreen Circle, Peoria, IL 61614.	City of Peoria Public Works Department, 3505 North Dries Lane, Peoria, IL 61604.	June 7, 2013	170536
Indiana:					
Boone (FEMA Docket No.: B–1306).	Town of Zionsville (12–05–6549P).	The Honorable Jeff Papa, President, Zionsville Town Council, 1100 West Oak Street, Zionsville, IN 46077.	1100 West Oak Street, Zionsville, IN 46077.	April 9, 2013	180016

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Fulton (FEMA Docket No.: B–1306).	City of Rochester (12–05–9647P).	The Honorable Mark Smiley, Mayor, City of Rochester, 320 Main Street, Rochester, IN 46975.	125 East 9th Street, Rochester, IN 46975	May 29, 2013	180071
Fulton (FEMA Docket No.: B–1306).	Unincorporated areas of Fulton County (12–05–9647P).	The Honorable Mark J. Rodriguez, President, Fulton County Board of Commissioners, 1784 Chickory Lane, Rochester, IN 46975.	125 East 9th Street Rochester, IN 46975	May 29, 2013	180070
Allen (FEMA Docket No.: B–1277).	Unincorporated areas of Allen County (12–05–1513P).	The Honorable Nelson Peters, President, Allen County Board of Commissioners, 200 East Berry Street, Suite 410, Fort Wayne, IN 46802.	1 East Main Street, Room 630, Fort Wayne, IN 46802.	November 13, 2012	180302
Allen (FEMA Docket No.: B–1277).	City of New Haven (12–05–1513P).	The Honorable Terry E. McDonald, Mayor, City of New Haven, 815 Lincoln Highway East, New Haven, IN 46774.	815 Lincoln Highway East, New Haven, IN 46774.	November 13, 2012	180004
Iowa:					
Black Hawk (FEMA Docket No.: B–1306).	City of Cedar Falls (12–07–2641P).	The Honorable Jon Crews, Mayor, City of Cedar Falls, 220 Clay Street, Cedar Falls, IA 50613.	220 Clay Street, Cedar Falls, IA 50613	May 31, 2013	190017
Michigan:					
Wayne (FEMA Docket No.: B–1306).	City of Taylor (12–05–9857P).	The Honorable Jeffrey P. Lamarand, Mayor, City of Taylor, 23555 Goddard Road, Taylor, MI 48180.	23555 Goddard Road, Taylor, MI 48180	May 30, 2013	260728
Minnesota:					
Lac Qui Parle (FEMA Docket No.: B–1306).	City of Dawson (12–05–2019P).	The Honorable Merlin Ellefson, Mayor, City of Dawson, 675 Chestnut Street, Dawson, MN 56232.	675 Chestnut Street, Dawson, MN 56232	May 9, 2013	270241
Lac Qui Parle (FEMA Docket No.: B–1306).	Unincorporated areas of Lac Qui Parle County (12–05–2019P).	The Honorable DeRon Brehmer, Chair, Lac Qui Parle County Board of Commissioners, 600 6th Street, Madison, MN 562256.	600 6th Street, Madison, MN 562256	May 9, 2013	270239
St. Louis (FEMA Docket No.: B–1306).	City of Duluth (12–05–3211P).	The Honorable Don Ness, Mayor, City of Duluth, 411 West First Street, Room 402, Duluth, MN 55802.	411 West First Street, Duluth, MN 55802	April 12, 2013	270421
Missouri:					
Greene (FEMA Docket No.: B–1306).	City of Springfield (12–07–2302P).	The Honorable Bob Stephens, Mayor, City of Springfield, 840 Boonville Avenue, Springfield, MO 65801.	840 Boonville Avenue, Springfield, MO 65801.	May 31, 2013	290149
Nebraska:					
Buffalo (FEMA Docket No.: B–1306).	City of Kearney (12–07–3246P).	The Honorable Stanley Clouse, Mayor, City of Kearney, 18 East 22nd Street, Kearney, NE 68847.	18 East 22nd Street, Kearney, NE 68847	May 9, 2013	310016
Ohio:					
Portage (FEMA Docket No.: B–1306).	City of Kent (12–05–6090P).	The Honorable Jerry T. Fiala, Mayor, City of Kent, 614 Pioneer Avenue, Kent, OH 44240.	930 Overholt Drive, Kent, OH 44240	April 29, 2013	390456
Oregon:					
Jackson (FEMA Docket No.: B–1306).	Unincorporated areas of Jackson County (12–10–0825P).	The Honorable Don Skundrick, Chair, Jackson County Board of Commissioners, 10 South Oakdale Avenue, Room 214, Medford, OR 97501.	10 South Oakdale Avenue, Medford, OR 97501.	April 5, 2013	415589
Yamhill (FEMA Docket No.: B–1306).	Unincorporated areas of Yamhill County (12–10–1146P).	The Honorable Leslie Lewis, Chair, Yamhill Board of Commissioners, 434 Northeast Evans Street, McMinnville, OR 97128.	535 Northeast 5th Street, McMinnville, OR 97128.	May 9, 2013	410249
Washington:					
Franklin (FEMA Docket No.: B–1306).	Unincorporated areas of Franklin County (12–10–0991P).	The Honorable Brad Peck, Chairman, Franklin County Board of Commissioners, 1016 North 4th Avenue, Pasco, WA 99301.	1016 North 4th Avenue, Pasco, WA 99301.	April 5, 2013	530044
Walla Walla (FEMA Docket No.: B–1306).	Unincorporated areas of Walla Walla County (12–10–0991P).	The Honorable Gregory A. Tompkins, Chairman, Walla Walla County Board of Commissioners, 314 West Main Street, Walla Walla, WA 99362.	314 West Main Street, Walla Walla, WA 99362.	April 5, 2013	530194
Wisconsin:					

State and county	Location and case No.	Chief executive officer of community	Community map repository	Effective date of modification	Community No.
Kewaunee (FEMA Docket No.: B–1306).	City of Kewaunee (12–05–5905P).	The Honorable John Blaha Jr., Mayor, City of Kewaunee, 107 Summers Circle-3, 388–4454, Kewaunee, WI 54216.	401 Fifth Street, Kewaunee, WI 54216	April 26, 2013	550215
Outagamie (FEMA Docket No.: B–1306).	Unincorporated areas of Outagamie County (12–05–7344P).	The Honorable Thomas Nelson, 410 South Walnut Street, Appleton, WI 54911.	410 South Walnut Street, Appleton, WI 54911.	June 3, 2013	550302
Sauk (FEMA Docket No.: B–1306).	City of Wisconsin Dells (12–05–7540P).	The Honorable Brian L. Landers, Mayor, City of Wisconsin Dells, 305 Bauer Court, Wisconsin Dells, WI 53965.	300 LaCrosse Street, Wisconsin Dells, WI 53965.	May 28, 2013	550065
Wood (FEMA Docket No.: B–1306).	City of Wisconsin Rapids (12–05–6906P).	The Honorable Zach Vruwink, Mayor, City of Wisconsin Rapids, 444 West Grand Avenue, Wisconsin Rapids, WI 54495.	Engineering Department, 444 West Grand Avenue, Wisconsin Rapids, WI 54495.	April 5, 2013	555587

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: May 17, 2013.

Roy E. Wright,

Deputy Associate Administrator for Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2013–13936 Filed 6–11–13; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4116–DR; Docket ID FEMA–2013–0001]

Illinois; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA–4116–DR), dated May 10, 2013, and related determinations.

DATES: *Effective Date:* June 6, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Illinois is hereby amended to include the Public Assistance program for the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 10, 2013.

Bureau, Clark, Crawford, DuPage, Fulton, Grundy, Henderson, Kendall, Knox, Lake, LaSalle, Livingston, Marshall, Mason, McHenry, Pike, Rock Island, Stark, and Woodford Counties for Public Assistance (already designated for Individual Assistance).

Adams, Mercer, Ogle, Putnam, and Warren Counties for Public Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households in Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–13942 Filed 6–11–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Internal Agency Docket No. FEMA–4116–DR; Docket ID FEMA–2013–0001]

Illinois; Amendment No. 2 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Illinois (FEMA–4116–DR), dated May 10, 2013, and related determinations.

DATES: *Effective Date:* May 31, 2013.

FOR FURTHER INFORMATION CONTACT: Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Illinois is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 10, 2013.

Brown, Calhoun, Clark, Douglas, Henry, Pike, Whiteside, and Winnebago Counties for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

W. Craig Fugate,

Administrator, Federal Emergency Management Agency.

[FR Doc. 2013–13931 Filed 6–11–13; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5693–N–03]

Implementation of the Privacy Act of 1974, as Amended; Privacy Act System of Records, Family Self-Sufficiency Program Demonstration Data

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: Pursuant to the Privacy Act of 1974 (U.S.C. 552a(e)(4)), as amended, and Office of Management and Budget (OMB), Circular No. A–130, notice is hereby given that the Department of Housing and Urban Development (HUD), Office of Policy Development and Research provides public notice regarding its Family Self-Sufficiency Program Demonstration Data. This study will allow the Department, and other participating agencies to evaluate the benefits and impacts gained from families participating in the Family Self Sufficiency program. The data sources evaluated under this program are gathered from Federal, state, and local agencies' databases. A more detailed description of the proposed system is contained in the purpose section of this notice.

DATES: *Effective Date:* This notice shall become effective, without further notice July 12, 2013, unless comments are received during or before this period which would result in a contrary determination.

Comments Due Date: July 12, 2013.

FOR FURTHER INFORMATION CONTACT: Donna Robinson-Staton, Chief Privacy Officer, 451 Seventh Street SW., Washington, DC 20410 (Attention: Capitol View Building, 4th Floor), telephone number: (202) 402–8073. [The above telephone number is not a toll free number.] A telecommunications device for hearing- and speech-impaired persons (TTY) is available by calling the Federal Information Relay Service's toll-free telephone number (800) 877–8339.

SUPPLEMENTARY INFORMATION: Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), Pursuant to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, notice is given that HUD proposes to establish a new system of records. The system report was submitted to the Office of Management and Budget (OMB), the Senate Committee on Homeland Security and Governmental Affairs, and the House Committee on Government Reform pursuant to Paragraph 4c of Appendix l to OMB Circular No. A–130, ''Federal Agencies Responsibilities for Maintaining Records About Individuals,'' July 25, 1994 (59 FR 37914).

Authority: 5 U.S.C. 552a; 88 Stat. 1896; 42 U.S.C. 3535(d).

Dated: May 31, 2013.

Barbara Elliott,

Acting Chief Information Officer.

SYSTEM OF RECORDS NO.: PD&R/RRE.02

SYSTEM NAME:

Family Self-Sufficiency Program Demonstration Data.

SYSTEM LOCATION:

MDRC 16 East 34th Street, New York, NY 10016–4326; Department of Housing and Urban Development, 451 7th St. SW., Washington DC 20410; Iron Mountain, 1101 Enterprise Drive, Royersford, PA 19468.

CATEGORIES OF INDIVIDUALS COVERED BY THIS SYSTEM:

Participants in the Family Self-Sufficiency Program Demonstration.

CATEGORIES OF RECORDS IN THE SYSTEM:

The dataset will contain the following categories of records:

1. Output of random assignment process: Identify treatment group status, sample ID and research ID.

2. Responses to baseline information form: This initial survey collects PII, including social security number, full name, date of birth, public housing authority household ID number, address, phone numbers, email addresses, and contact information of family or friends. In addition, it will collect demographic data, family status, household composition, employment status, and income.

3. Responses to follow-up survey: Respondents' subjective assessments of FSS; respondents' experiences with other public housing programs; respondents' earning of degrees and credentials; involvement in education, training, and employment services; respondent and household income; material hardship; family well-being; savings, debt, and financial behaviors; household demographics; housing circumstances and conditions.

4. Administrative data: Data on households available through HUD administrative data collections will be brought into the dataset directly from participating public housing authorities and extracted from HUD's Inventory Management System, including information pertaining to family structure, household size, household assets, household income, total tenant payment and subsidy amount, FSS escrow account eligibility, timing and amount of FSS escrow account contributions, withdrawals from FSS escrow account, eligibility for Section 8 housing, residence status in public housing, and participation in other HUD programs.

5. Management information system data: When necessary, each study site will include information about FSS pre-employment, education, and training services providers will be collected, including service type, service referral, start and end dates, end reason, degree/credential receipt, and supportive services payment types.

6. Data from State Unemployment Insurance systems and other administrative systems outside of HUD: In addition to the data collected through the follow-up survey, the FSS Demonstration Data will also include quarterly data drawn from the Unemployment Insurance (UI) system on employment, earnings, and UI benefit receipt. It may also include data on receipt of Supplemental Nutrition Assistance Program (SNAP) benefits and Temporary Assistance to Needy Families (TANF) benefits collected from the responsible entities in each study site.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 502(g) of the Housing and Urban Development Act of 1970 (Public Law 91–609) (12 U.S.C. 1701z-1; 1701z-2(d) and (g)).

PURPOSE(S):

The purpose of the FSS Demonstration is to evaluate the impact of the FSS program. The FSS Demonstration is a random-assignment study to evaluate the effectiveness of the Family Self-Sufficiency (FSS) Program. FSS has operated since 1992 and serves voucher holders and residents of public housing. The FSS program offers participants case management plus an escrow account in which they must deposit a proportion of any increased earnings during the time they stay in the program. The FSS program aims to help participants increase their earnings. To date, HUD previously funded two studies of the FSS program, but neither can tell us how well families would have done in the absence of the program. The FSS Demonstration will compare FSS participants to nonparticipants in terms of employment, earnings and housing stability over several years. Because participants and non-participants will be randomly assigned instead of self-selected, the FSS Demonstration findings will allow us to attribute participant gains to the impact of the program. This study will provide

critical information for developing policies that truly support families toward self-sufficiency. The findings of the FSS Demonstration can inform decisions about the modification or expansion of the FSS program. Furthermore, the FSS Demonstration is in direct service of the mission of HUD's Office of Policy Development and Research, which is to ''inform policy development and implementation to improve life in American communities through conducting, supporting, and sharing research, surveys, demonstrations, program evaluations, and best practices.'' In sum, the purposes of the FSS Demonstration are (1) to find out if the FSS program helps families achieve self-sufficiency and (2) to provide policy makers with insight into how policy can best help families achieve self-sufficiency.

ROUTINE USE OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, HUD may disclose information contained in this system of records without the consent of the subject individual in accordance with the following discretionary disclosures set forth by the **Federal Register** Notice ''HUD's Routine Use Inventory'' [Docket No. FR–5613–N–07] published on 7/17/2012 [1] when such disclosure is compatible with the purpose for which the record was collected, providing that approval is obtained from the system manager. Routine uses applicable to the FSS Demonstration Data System include:

(1) To a recipient who has provided the agency with advance adequate written assurance that the record will be used solely as a statistical research or reporting record, and the record is to be transferred in a form that is not individually identifiable;

(2) To the National Archives and Records Administration (NARA) and the General Services Administration (GSA) for records having sufficient historical or other value to warrant its continued preservation by the United States Government, or for inspection under authority of Title 44, Chapter 29, of the United States;

(3) To a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual;

(4) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities including but not limited to state and local governments, and other research institutions or their parties, other entities and their agents with whom HUD has a contract, service agreement, grant, or cooperative agreement, when necessary to accomplish an agency function related to a system of records for the purposes of statistical analysis and research in support of program operations, management, performance monitoring, evaluation, risk management, and policy development, or otherwise to support the Department's mission. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits or privileges of specific individuals. The results of matched information may not be disclosed in identifiable form;

(5) To the Department of Justice (DOJ) when seeking legal advice for a HUD initiative or in response to DOJ's request for the information, after either HUD or DOJ determine that such information is relevant to DOJ's representatives of the United States or any other components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that disclosure of the records to the DOJ is a use of the information contained in the records that is compatible with the purpose for which HUD collected the records;

(6) HUD on its own may disclose records in this system of records in legal proceeding before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which HUD collected the records;

(7) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency which maintains the record specifying the particular portion desired and the law enforcement activity for which the record is sought; and

(8) To appropriate agencies, entities, and persons when: (a) HUD suspects or has confirmed that the security or confidentiality of information in a system of records has been compromised; (b) HUD has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of systems or programs (whether maintained by HUD or another agency or entity) that rely upon the compromised information; and (c) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with HUD's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm for purposes of facilitating responses and remediation efforts in the event of a data breach.

STORAGE:

Records are stored on secure servers. System users are not allowed to download, keep, or process individual-level data on the hard drives of their MDRC work stations. Archived study data will be stored on secure servers, and the IRON Mountain Storage facility.

RETRIEVABILITY:

Records will be retrieved by social security number and/or unique study identifier.

SAFEGUARDS:

Access to any server, security, storage, backup, and infrastructure equipment is monitored, restricted to only those with a need-to-have system access, including being secured by administrative password and authentication methods. All system users are required to sign a confidentiality pledge to abide by corporate policies and by HUD policies. There are no paper-based records associated with this study.

RETENTION AND DISPOSAL:

Records (electronic data) files are maintained in accordance with HUD Records Disposition Schedule 67.9.b and 67.9.f;[2] this schedule requires that records be retained or archived for 6 years. As such, when projects are satisfactorily closed and records are no longer needed for administrative purposes, the records can be destroyed when the destruction date is reached. Manual records are destroyed by shredding or burning; electronic records are destroyed in accordance with HUD's IT Security Handbook 2400.25, Section 4.7.6.[3]

SYSTEM MANAGER(S) AND ADDRESS:

Director, Division of Program Evaluation, Department of Housing and Urban Development, Office of Policy Development and Research, 451 Seventh Street SW., Room 8120, Washington, DC 20410.

NOTIFICATION AND RECORD ACCESS PROCEDURE:

For information, assistance, or inquiry about the existence of records, contact

[1] *http://portal.hud.gov/hudportal/documents/huddoc?id=append1.pdf.*

[2] *http://portal.hud.gov/hudportal/documents/huddoc?id=22256x67ADMH.pdf.*

[3] *http://portal.hud.gov/hudportal/documents/huddoc?id=240025CIOH.pdf.*

the Chief Privacy Officer, Department of Housing and Urban Development, 451 Seventh Street SW., Room 4156, Washington, DC 20410. (Attention: Capitol View Building, 4th Floor). Provide verification of your identity by providing two proofs of official identification. Your verification of identity must include your original signature and must be notarized. The Department's rules for providing access to records to the individual concerned appear in 24 CFR part 16.

CONTESTING RECORD PROCEDURES:

The procedures for requesting amendment or correction of records appear in 24 CFR part 16. If additional information is needed, contact:

(i) In relation to contesting contents of records, the Privacy Act Officer at HUD, 451 Seventh Street SW., Room 4178 (Attention: Capitol View Building, 4th Floor), Washington, DC 20410;

(ii) In relation to appeals of initial denials, HUD, Departmental Privacy Appeals Officer, Office of General Counsel, 451 Seventh Street SW., Washington, DC 20410.

RECORD SOURCE CATEGORIES:

(1) Output of random assignment process, (2) Responses to baseline information form, (3) Responses to follow-up survey, (4) Administrative data, (5) Management information system data from public housing agencies, and (6) Data from administrative systems, including State Unemployment Insurance and entities responsible for Supplemental Nutrition Assistance Program (SNAP) benefits and Temporary Assistance to Needy Families (TANF) in each study site.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

None.

[FR Doc. 2013–13974 Filed 6–11–13; 8:45 am]

BILLING CODE 4210–67–P

INTER-AMERICAN FOUNDATION

Sunshine Act Meetings

TIME AND DATE: June 24, 2013, 9:00 a.m.–1:00 p.m.

PLACE: 1331 Pennsylvania Ave. NW., 12th floor north, Suite 1200, Washington, DC 20004.

STATUS: Open session

Matters To Be Considered

- Approval of the Minutes of the March 25, 2013, Meeting of the Board of Directors
- Management Report
- Advisory Council Report
- Donor Engagement

Portions To Be Open To The Public

- Approval of the Minutes of the March 25, 2013, Meeting of the Board of Directors
- Management Report
- Advisory Council Report
- Donor Engagement

CONTACT PERSON FOR MORE INFORMATION: Paul Zimmerman, General Counsel, (202) 683–7118.

Paul Zimmerman,

General Counsel.

[FR Doc. 2013–14044 Filed 6–10–13; 4:15 pm]

BILLING CODE 7025–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–FHC–2013–N128;FXFR1334088TWG0W4–123–FF08EACT00]

Trinity Adaptive Management Working Group; Public Meeting, Teleconference and Web-Based Meeting

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We, the U.S. Fish and Wildlife Service, announce a public meeting, teleconference and web-based meeting of the Trinity Adaptive Management Working Group (TAMWG).

DATES: *Public meeting, Teleconference, and web-based meeting:* Tuesday June 25, 2013, from 9:30 a.m. to 5 p.m. Pacific time. *Deadlines:* For deadlines and directions on registering to listen to the meeting by phone, listening and viewing on the Internet, submitting written material, please see ''Public Input'' under **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The meeting will be held at the Weaverville Fire District, 125 Bremer Street, Weaverville, CA 96093. You may participate in person or by teleconference or web-based meeting from your home computer or phone.

FOR FURTHER INFORMATION CONTACT: Elizabeth W. Hadley, Redding Electric Utility, 777 Cypress Avenue, Redding, CA 96001; telephone: 530–339–7327; email: *ehadley@reupower.com.*

SUPPLEMENTARY INFORMATION: In accordance with the requirements of the Federal Advisory Committee Act, 5 U.S.C. App., we announce that the Trinity Adaptive Management Working Group (TAMWG) will hold a meeting.

Background

The TAMWG affords stakeholders the opportunity to give policy, management, and technical input concerning Trinity River (California) restoration efforts to the Trinity Management Council (TMC). The TMC interprets and recommends policy, coordinates and reviews management actions, and provides organizational budget oversight.

Meeting Agenda

- Designated Federal Officer (DFO) updates,
- TMC Chair report,
- Executive Director's report,
- 2013 design update,
- Scientific Advisory Board phase 1 review,
- Ethics coordination,
- Update from TRRP workgroups,
- Update on Decision Support System implementation, and
- Bid contracting.

The final agenda will be posted on the Internet at *http://www.fws.gov/arcata.*

Public Input

If you wish to	You must contact Elizabeth Hadley (**FOR FURTHER INFORMATION CONTACT**) no later than
Listen to the teleconference/web-based meeting via telephone or Internet	June 18, 2013.
Submit written information or questions for the TAMWG to consider during the teleconference	June 18, 2013.

Submitting Written Information or Questions

Interested members of the public may submit relevant information or questions for the TAMWG to consider during the meeting. Written statements must be received by the date listed in ''Public Input,'' so that the information may be available to the TAMWG for their consideration prior to this teleconference. Written statements must be supplied to Elizabeth Hadley in one of the following formats: One hard copy with original signature, and one electronic copy with original signature, and one electronic copy via email (acceptable file formats are Adobe Acrobat PDF, MS Word, PowerPoint, or rich text file).

Registered speakers who wish to expand on their oral statements, or those who wished to speak but could not be accommodated on the agenda, may submit written statements to Elizabeth Hadley up to 7 days after the meeting.

Meeting Minutes

Summary minutes of the meeting will be maintained by Elizabeth Hadley (see **FOR FURTHER INFORMATION CONTACT**). The minutes will be available for public inspection within 90 days after the meeting, and will be posted on the TAMWG Web site at *http://www.fws.gov/arcata*.

Dated: June 5, 2013.

Joseph C. Polos,

Supervisory, Fish Biologist, Arcata Fish and Wildlife Office, Arcata, California.

[FR Doc. 2013–13900 Filed 6–11–13; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLOR957000–L63100000–HD0000–13XL1165AF: HAG13–0209]

Filing of Plats of Survey: Oregon/Washington

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The plats of survey of the following described lands are scheduled to be officially filed in the Bureau of Land Management, Oregon State Office, Portland, Oregon, 30 days from the date of this publication.

Willamette Meridian

Oregon

T. 39 S., R. 5 E., accepted May 17, 2013
T. 38 S, R. 6 E., accepted May 17, 2013

Washington

Tps. 32 and 33 N., R. 10 E., accepted May 20, 2013

ADDRESSES: A copy of the plats may be obtained from the Public Room at the Bureau of Land Management, Oregon State Office, 333 SW 1st Avenue, Portland, Oregon 97204, upon required payment.

FOR FURTHER INFORMATION CONTACT: Kyle Hensley, (503) 808–6132, Branch of Geographic Sciences, Bureau of Land Management, 333 SW 1st Avenue, Portland, Oregon 97204. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 to contact the above individual during normal business hours. The FIRS is available 24 hours a day, 7 days a week, to leave a message or question with the above individual. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: A person or party who wishes to protest against this survey must file a written notice with the Oregon State Director, Bureau of Land Management, stating that they wish to protest. A statement of reasons for a protest may be filed with the notice of protest and must be filed with the Oregon State Director within thirty days after the protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Mary J.M. Hartel,

Chief Cadastral Surveyor of Oregon/Washington.

[FR Doc. 2013–13901 Filed 6–11–13; 8:45 am]

BILLING CODE 4310–33–P

DEPARTMENT OF INTERIOR

National Park Service

[NPS–NERO–FLNI–13257; PPMPSAS1Z.Y00000]

Notice of Flight 93 Advisory Commission Meeting Change

AGENCY: National Park Service, Interior.

ACTION: Notice of Public Meeting Date Change.

SUMMARY: Notice is hereby given of a meeting of the Flight 93 Advisory Commission, on September 10, 2013, Flight 93 National Memorial Office, 109 West Main Street, Somerset, PA 15501. This is a date change from what was announced in the **Federal Register** on January 29, 2013.

DATES: The public meeting of the Advisory Commission will be held on Tuesday, September 10, 2013, at 10:00 a.m. (EASTERN).

Location: The meeting will be held at the Flight 93 National Memorial Office, 109 West Main Street Suite 104, Somerset, PA 15501.

Agenda

The Commission meeting will consist of the following:

1. Opening of Meeting, Review and Approval of Commission Minutes
2. Reports
3. Old Business
4. New Business
5. Public Comments
6. Closing Remarks

FOR FURTHER INFORMATION CONTACT: Further information concerning this meeting may be obtained from the Jeff Reinbold, Superintendent, Flight 93 National Memorial, P. O. Box 911, Shanksville, PA 15560, telephone (814) 893–6322.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Interested persons may make oral/written presentations to the Commission or file written statements. Such requests should be made to the Superintendent at least seven days prior to the meeting. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: June 6, 2013.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2013–13912 Filed 6–11–13; 8:45 am]

BILLING CODE 4310–WV–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[A10–1999–6000–100–00–0–0–3, 3501000]

Availability of Final Environmental Impact Statement; Bunker Hill Groundwater Basin, Riverside-Corona Feeder Project; San Bernardino and Riverside Counties, CA

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Reclamation and the Western Municipal Water District have completed a final Supplemental Environmental Impact Report/Environmental Impact Statement (SEIR/EIS) for the proposed Riverside-Corona Feeder Project.

DATES: The Bureau of Reclamation will not make a decision on the proposed project until at least 30 days after the Notice of Availability is published by the Environmental Protection Agency.

ADDRESSES: The final SEIR/EIS can be downloaded from our Web site: *http://www.usbr.gov/lc/socal/envdocs.html.* Printed copies are available for public review and inspection at the following locations:

- Bureau of Reclamation, Lower Colorado Regional Office, 500 Fir Street Boulder City, Nevada 89005.
- Bureau of Reclamation, Southern California Area Office, 27708 Jefferson Avenue Suite 202, Temecula, California 92590.
- Western Municipal Water District, 14205 Meridian Parkway, Riverside, California, 92518.

FOR FURTHER INFORMATION CONTACT: Ms. Amy Witherall, Project Manager, SCAO–7300, Bureau of Reclamation, Southern California Area Office, 27708 Jefferson Avenue Suite 202, Temecula, CA 92590; telephone: (951) 695–5310; facsimile: (951) 695–5319; or email: *awitherall@usbr.gov.*

SUPPLEMENTARY INFORMATION: The Federal action will provide funds for a proposed aquifer storage and recovery project, including new groundwater wells and a 28-mile water pipeline system with pump stations and a reservoir storage tank. The project is intended to improve the reliability of Western's water supply through managed storage, extraction and distribution of local and imported water supplies, using available capacity in the Bunker Hill Groundwater Basin and the Chino Basin.

We issued a Notice of Intent on February 24, 2010 (75 FR 8395) and published a Notice of Availability for the draft SEIR/EIS on January 20, 2011 (76 FR 3655). The Environmental Protection Agency Notice of Availability was published on January 28, 2011 (76 FR 5156). The Western Municipal Water District filed a Notice of Determination on February 16, 2012, in accordance with the California Environmental Quality Act.

Dated: June 4, 2013.

Terrance J. Fulp,

Regional Director, Lower Colorado Region.

[FR Doc. 2013–13937 Filed 6–11–13; 8:45 am]

BILLING CODE 4310–MN–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–749 (Third Review)]

Persulfates From China; Notice of Commission Determination To Conduct a Full Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it will proceed with a full review pursuant to section 751(c)(5) of the Tariff Act of 1930 (19 U.S.C. 1675(c)(5)) to determine whether revocation of the antidumping duty order on persulfates from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time. A schedule for the review will be established and announced at a later date. For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

DATES: *Effective Date:* June 4, 2013.

FOR FURTHER INFORMATION CONTACT: Christopher J. Cassise (202–708–5408), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On June 4, 2013, the Commission determined that it should proceed to a full review in the subject five-year review pursuant to section 751(c)(5) of the Act. The Commission found that the domestic interested party group response to its notice of institution (78 FR 13891, March 1, 2013) was adequate and that the respondent interested party group response was inadequate. The Commission found, however, that other circumstances warranted conducting a full review.[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's Web site.

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: June 6, 2013.

Lisa R. Barton,

Acting Secretary to the Commission.

[FR Doc. 2013–13873 Filed 6–11–13; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Comprehensive Environmental Response, Compensation and Liability Act

On June 6, 2013, the Department of Justice lodged a proposed settlement entitled ''Interim Past Costs Consent Decree'' (the ''Consent Decree'') with the United States District Court for the District of Montana in the case of *United States* v. *Atlantic Richfield Company et al.,* Civil Action No. CV–89–39–BU–SEH. The Consent Decree settles the United States' claim for certain response costs incurred under Section 107(a) of the Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. 9607(a), in connection with the environmental remediation of the Anaconda Smelter NPL Superfund Site and the Warm Springs Ponds Operable Units (the ''Sites''), near

[1] Chairman Irving A. Williamson dissenting.

Anaconda, Montana. Under the terms of the Consent Decree, Atlantic Richfield Company will pay the United States $21,030,000 for EPA's costs incurred in responding to releases and threatened releases of hazardous substances at the Sites from August 1, 2002 through December 31, 2010, and for the costs of Department of Justice enforcement efforts paid in connection with the Sites and other Superfund sites within Montana's Clark Fork River Basin from April 29, 2007 through December 31, 2010.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Atlantic Richfield Company, et al.,* D.J. Ref. No. 90–11–2–430. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/Consent_Decrees.htm.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $6.00 (25 cents per page reproduction cost) payable to the United States Treasury.

Robert Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2013–13903 Filed 6–11–13; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Third Amendment to Consent Decree Under the Clean Water Act

On June 5, 2013, the Department of Justice lodged a proposed Third Amendment to 2006 Consent Decree with the United States District Court for the Southern District of Indiana in the lawsuit entitled *United States and State of Indiana* v. *City of Indianapolis, Indiana,* Civil Action No. 1:06–cv–01456.

On December 19, 2006, the District Court had approved and entered a Consent Decree among the United States, the State of Indiana, and the City of Indianapolis, Indiana, which resolved various alleged violations of the Clean Water Act. The Consent Decree obligated the City of Indianapolis to implement certain combined sewer overflow control measures in accordance with a Long Term Control Plan. Subsequent Consent Decree Amendments refined these obligations. In 2011, the City's wastewater system was sold to CWA Authority, Inc., an Indiana nonprofit corporation. The proposed Third Amendment to 2006 Consent Decree extends the City's obligations under the Consent Decree to CWA Authority.

The publication of this notice opens a period for public comment on the proposed Third Amendment to 2006 Consent Decree. Comments should be addressed to the Acting Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States and State of Indiana* v. *City of Indianapolis, Indiana,* D.J. Ref. No. 90–5–1–1–07292. All comments must be submitted no later than 30 days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General U.S. DOJ—ENRD P.O. Box 7611 Washington, D.C. 20044–7611.

During the public comment period, the proposed Third Amendment to 2006 Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the proposed Third Amendment to 2006 Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $3.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen M. Katz,

Assistant Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2013–13874 Filed 6–11–13; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under The Clean Water Act

On June 6, 2013, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Southern District of Florida in the lawsuit entitled *United States, State of Florida and State of Florida Department of Environmental Protection* v. *Miami-Dade County,* Civil Action No. 1:12-cv-24400–FAM.

The lawsuit was filed against Miami-Dade County on December 13, 2012 pursuant to Clean Water Act (''CWA'') Sections 309(b) and (d) and 504, 33 U.S.C. 1319(b) and (d) and 1364, and the Florida Air and Water Pollution Control Act, Fla. Stat. Chapter 403, seeking penalties and injunctive relief under Sections 301 and 402 of the CWA, 33 U.S.C. 1311 and 1342, and under Fla. Stat. §§ 403.121, 403.131, 403.141 and 403.161 for (1) unpermitted discharges of untreated sewage from the sanitary sewer system into navigable waters and Florida waters; (2) failure to comply with certain National Pollutant Discharge Elimination System (''NPDES'') effluent permit conditions; (3) failure to comply with standard NPDES permit conditions, including proper operation and maintenance of the sewer system from December 2007 to the filing of the Complaint; and (4) imminent and substantial endangerment to health and welfare of persons, as well as irreparable injury to human health, waters, and property, including animal, plant and aquatic life of the state, due to the numerous sanitary sewer overflows; and the continued threat of failure of Miami-Dade's aged and deteriorated force mains, including the 54-inch force main underneath Government Cut between Fisher Island and south of the City of Miami Beach that conveys untreated wastewater from the City of Miami Beach under Biscayne Bay to the Central District Wastewater Treatment Plant.

The proposed Consent Decree includes an estimated $1.55 billion in capital improvements to Miami-Dade's wastewater collection and transmission system over the next 15 years, including

sewer assessment, rehabilitation, repair, and replacement work on force mains, sewer lines, manholes, and pumps, and rehabilitation of all three wastewater treatment plants. Miami-Dade has also agreed to implement a number of EPA sewer maintenance and repair programs which EPA believes will dramatically reduce the incidence and severity of sanitary sewer overflows. Miami-Dade also has agreed to pay a penalty of $978,100, of which $511,800 will be paid to the United States, and $466,300 will be paid to Florida. Miami-Dade has also agreed to complete a Supplemental Environmental Project valued at $2,047,200.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States, State of Florida and State of Florida Department of Environmental Protection* v. *Miami-Dade County,* Civil Action No. 1:12-cv-24400–FAM, D.J. Ref. No. 90–5–1–1–4022/1. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, D.C. 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.usdoj.gov/enrd/Consent_Decrees.html.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $81 (25 cents per page reproduction cost) payable to the United States Treasury. For a paper copy of the Consent Decree without the appendices, the cost is $25.25.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2013–13913 Filed 6–11–13; 8:45 am]

BILLING CODE 4410–CW–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Employment Retention Inventory Validation

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a cooperative agreement.

SUMMARY: The National Institute of Corrections (NIC) is soliciting proposals from organizations, groups, or individuals to enter into a cooperative agreement for a 24-month period to begin no later than September 15, 2013. Work under this cooperative agreement will involve the evaluation of the Employment Retention Inventory (ERI), which supports the case management efforts of workforce development practitioners. Specifically, the goal of this project is to determine whether the ERI effectively identifies the precursors, obstacles, and personality traits that influence an offender's separation from the workforce. In addition, this project will explore the relationship between offender employment retention and recidivism. The major deliverables of this project include (1) the use of a system to capture and evaluate data and (2) a written report that summarizes project findings, recommendations, and potential next steps. This project will be a collaborative venture with the NIC Community Services Division.

NIC Opportunity Number: 13CS11. This number should appear in the reference line in your cover letter, on Standard Form 424 in section 11 with the title of your proposal, and in the right justified header of your proposal.

Number of Awards and Funds Available: Under this solicitation, one (1) award will be made. The total amount of funds available under this solicitation is $150,000.00.

Applications: All applicants must be submitted electronically via *http://www.grants.gov*. Hand delivered, mailed, faxed, or emailed applications will not be accepted.

DATES: Application must be submitted before midnight on Monday, July 8, 2013.

Authority: Public Law 93–415

Eligibility of Applicants: An eligible applicant is any public or private agency, educational institution, organization, individual or team with expertise in the described areas.

SUPPLEMENTARY INFORMATION:

Background: In 2010, the National Institute of Corrections entered into an 18-month cooperative agreement to develop a competency-based training curriculum to provide practitioners with the knowledge and skills needed for the provision of employment retention services for those identified as having barriers to sustained employment. This curriculum, based on evidence-based practices, combined cognitive behavioral principles with motivational interviewing techniques to broaden the ability of the practitioner to develop strategies for change while improving offender outcomes through collaboration with stakeholders; practitioners increased their knowledge in employment retention, career development theory and application, facilitation skills, and transitional intervention. Combining these two research-based methods helps the offender create a solid foundation for self-exploration and change—guided by a ''spirit'' that supports the offender's self-examination to resolve ambivalence to change. In addition, the ERI was developed to identify precursors to job loss and/or recidivism while creating a process for connecting targeted populations to specialized services that address their risk for job loss and recidivism successfully.

Offender workforce development programing should target offenders found to be at medium/high risk for job loss and return to criminal activities. It should be based on standardized and validated risk and specialized assessment instruments. Practitioners having the competencies to assist offenders in becoming successful at maintaining a long-term connection to the workforce will be able to assess those at high risk for job loss, identify specific indicators, and analyze the chain of events and behaviors that lead to separation from the workforce and recidivism. This project will contribute to the body of knowledge currently available specific to offender workforce development while also contributing to the shaping of effective policy and practice for establishing and maintaining employment services that successfully engage medium- to high-risk offenders.

Scope of Work: The tasks to be performed under this cooperative agreement include (1) review of documents directly related to NIC's Employment Retention Initiative, (2) participation in an initial meeting with designated NIC staff for a project overview and preliminary planning session, (3) identification and/or justification of the research design methodology, (4) identification of target populations, (5) determination of data measurements and collection procedure,

(6) development of a final report that summarizes the project—suggesting next steps and/or follow up work specific to NIC's Employment Retention Initiative, (7) participation in a national platform to discuss lessons learned, and (8) a presentation on findings to NIC executive staff.

Deliverables: Under this cooperative agreement, the awardee is expected to produce (1) eight quarterly reports reflecting the progress of the project, (2) an electronic system to capture and track data, (3) a written report reflecting project findings and/or recommendations, and (4) an electronic presentation reflecting project findings and/or recommendations.

FOR FURTHER INFORMATION CONTACT: All technical or programmatic questions concerning this announcement should be directed to P. Elizabeth Taylor, Correctional Program Specialist, National Institute of Corrections who may be reached by email at *petaylor@bop.gov.* In addition to the direct reply, all questions and responses will be posted on NIC's Web site at *www.nicic.gov* for public review (the names or affiliations of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation.

Application Requirements: Application Requirements: Applications should be typed, double spaced, in 12-point font, and reference the project by the ''NIC Opportunity Number'' 13CS11 and title in this announcement, ''Employment Retention Inventory Validation.'' The package must include: a cover letter that identifies the audit agency responsible for the applicant's financial accounts as well as the audit period or fiscal year that the applicant operates under (*e.g.,* July 1 through June 30); a concisely written program narrative, not to exceed 30 numbered pages, in response to the statement of work, and a detailed budget with a budget narrative explaining projected costs. Applicants may submit a description of the project teams' qualifications and expertise relevant to the project, but should not attach lengthy resumes. Attachments to the proposal describing your organization or examples of other past work beyond those specifically requested above are discouraged.

The following forms must also be included: OMB Standard Form 424, Application for Federal Assistance; OMB Standard Form 424A, Budget information—Non-Construction Programs; OMB Standard Form 424B, Assurances—Non-Construction Programs (these forms are available at *http://www.grants.gov*) and DOJ/NIC Certification Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and the Drug-Free Workplace Requirements (available at *http://nicic.gov/Downloads/General/certif-frm.pdf*

Failure to supply all required forms with the application package may result in disqualification of the application from consideration.

Note: NIC will NOT award a cooperative agreement to an applicant who does not have a Dun and Bradstreet Database Universal Number (DUNS) and is not registered in the Central Contractor Registry (CCR).

A DUNS number can be received at no cost by calling the dedicated toll-free DUNS number request line at 1–800–333–0505 (if you are a sole proprietor, you would dial 1–866–705–5711 and select option 1).

Registration in the CRR can be done online at the CCR Web site: *http://www.bpn.gov/ccr.* A CCR Handbook and worksheet can also be reviewed at the Web site.

Review Considerations: Applications received under this announcement will be subject to the NIC Review Process. Proposals which fail to provide sufficient information to allow evaluation under the criteria below may be judged non-responsive and disqualified.

The criteria for the evaluation of each application will be as follows:

Programmatic (40%)

Are all of the project tasks adequately discussed? Is there a clear statement of how each task will be accomplished to include the overall project goal(s), major tasks to achieve the goals(s), the strategies to be employed in completing the tasks, required staffing, and other required resources? Are there any approaches, techniques, or design aspects proposed that are new to NIC and will enhance the project?

Organizational (35%)

Do the proposed project staff members possess the skills, knowledge, and expertise necessary to complete the tasks listed under the scope of work? Does the applicant organization, group, or individual have the organizational capacity to achieve all project tasks? Does the proposal contain project management and staffing plans that are realistic and sufficient to complete the project within the project time frame?

Project Management/Administration (25%)

Does the applicant identify reasonable objectives, milestones, and measures to track progress? If consultants and/or partnerships are proposed, is there a reasonable justification for their inclusion in the project, and a clear structure to ensure effective coordination? Is the proposed budget realistic, does it provide a sufficient cost detail/narrative, and does it represent good value relative to the anticipated results?

Specific Requirements: Documents or other media that are produced under this award must follow these guidelines: Prior to the preparation of the final draft of any document or other media, the awardee must consult with NIC's Writer/Editor concerning the acceptable formats for manuscript submissions and the technical specifications for electronic media. For all awards in which a document will be a deliverable, the awardee must follow the guidelines listed herein, as well as follow the Guidelines for Preparing and Submitting Manuscripts for Publication as found in the ''General Guidelines for Cooperative Agreements,'' which can be found on our Web site at *www.nicic.gov/cooperativeagreements.*

All final documents and other materials submitted under this project must meet the federal government's requirement for Section 508 accessibility, including those provisions outlined in 1194 Subpart B, Technical Provisions; Subpart C, Functional Performance Criteria; and Subpart D, Documentation and Support. NIC's government product accessibility template (see *www.nicic.gov/section508*) outlines the agency's minimum criteria for meeting this requirement; a completed form attesting to the accessibility of project deliverables should accompany all submissions.

Note Concerning Catalog of Federal Domestic Assistance Number: Since this application is classified under Training and Staff Development, enter 16.601 in section 10 of the SF–424. You are not subject to the provisions of Executive Order 12372 and should check Box b. in section 16.

Robert Brown, Jr.,

Acting Director, National Institute of Corrections.

[FR Doc. 2013–13949 Filed 6–11–13; 8:45 am]

BILLING CODE 4410–36–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Corrections-Specific Resources for Extended Stakeholder Audiences

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a cooperative agreement.

SUMMARY: The National Institute of Corrections (NIC) is soliciting proposals from organizations, groups, or individuals to enter into a cooperative agreement for an 18-month period to begin no later than September 15, 2013. Work under this cooperative agreement will involve the development of a series of resources dedicated to addressing the corrections-specific frequently asked questions of its extended stakeholder audiences, including family and community-based constituency groups. Sample content may include original feature writing, creation of fact sheets, audio podcasts, videos, and/or photography. This project will be a collaborative venture with the NIC Research and Information Services Division.

NIC Opportunity Number: 13RE3. This number should appear in the reference line in your cover letter, on Standard Form 424 in section 11 with the title of your proposal, and in the right justified header of your proposal.

Number of Awards and Funds Available: Under this solicitation, one or more awards will be made. The total amount of funds available under this solicitation is $50,000.00.

Applications: All applicants must be submitted electronically via *http://www.grants.gov.* Hand delivered, mailed, faxed, or emailed applications will not be accepted.

DATES: Applications must be submitted before midnight on Monday, July 1, 2013.

Authority: Public Law 93–415.

Eligibility of Applicants: An eligible applicant is any public or private agency, educational institution, organization, individual or team with expertise in the described areas.

SUPPLEMENTARY INFORMATION:

Background: Under United States Public Law 93–415, the National Institute of Corrections was assigned with authority by Congress to ''serve as a clearinghouse and information center for the collection, preparation, and dissemination of information on corrections.'' By this authority, the National Institute of Corrections has become one of the largest national repositories for corrections-related information. Under this cooperative agreement, the awardee will develop materials designed to provide corrections-related information to extended stakeholder audiences.

Providing these resources will help reduce misconceptions among stakeholders about the nature and role of corrections in a community, as part of a local government structure, and as a participant in ensuring the public safety, public health, and general welfare of citizens. In addition, these resources will help correctional audiences, their stakeholders, and related community partners make informed choices in the future about the correctional laws and policies in their local area that affect them.

A proposal responsive to this solicitation should, at a minimum, include evidence of understanding that making accurate information available about the criminal justice system can help increase knowledge among stakeholders about corrections and related criminal justice operations. A proposal should also include evidence of the ability to create content, such as original feature writing, fact sheets, audio podcasts, videos, mobile apps, interactive maps, and/or photography, etc. that can be used as part of a systematic public education program.

Experience in corrections or a journalism-related occupation is not required. Most valued is an applicant's ability to translate criminal justice information accurately in plain language for the general public. The ability to write long-form as well as shorter pieces of content is required. The applicant must have a firm command of writing skills, fact gathering, and research.

In addition, expertise in some aspect of media production (Web, mobile, broadcast, social media, etc.) is required. The applicant must be able to supply material, such as audio, photo, video, mobile application, etc., to ''advance the story,'' giving those who read feature material an opportunity to engage actively and in depth with a topic.

A proposal should also reveal the applicant's ability and experience in working under weekly or daily deadlines and adhering to regular content development schedules.

Scope of work: Tasks to be performed through this cooperative agreement include (1) conducting background research using primary and secondary sources, (2) writing original content in a consumer friendly style, (3) developing interactive content, such as video, podcast, mobile application, or other multimedia material, (4) revising material as needed to adhere to agency specifications, (5) surveying current topics in corrections and proposing items to cover, and (6) planning and adhering to a content development schedule created in consultation with NIC staff.

This project will be completed in conjunction with the NIC Research and Information Services Division; however, the awardee will be expected to work closely with all NIC staff and contractors as needed on all aspects of the project.

The awardee will participate in an initial meeting with designated NIC staff for a project overview and preliminary planning. Additionally, the awardee will meet routinely with NIC staff to discuss the activities noted in the project timeline submitted during the course of the cooperative agreement. Meetings will be held weekly and may be conducted via telephone, webinar, and/or videoconference with at least one onsite as agreed upon by NIC and the awardee. Some travel expenses may be covered by NIC and therefore are negotiable depending on the meeting and/or awardee's location.

Deliverables: Deliverables expected be produced under this cooperative agreement include at a minimum (1) a final report that summarizes the project and provides recommendations for follow up work, (2) 52 weeks of weekly feature articles (800 to 2,500 words) (content only) describing or explaining concepts in corrections, (3) 26 weeks of bi-weekly media (such as audio, photo, video, mobile application, etc.) supporting feature content, (4) 12 months of monthly fact sheets (content only) describing or explaining concepts in corrections.

FOR FURTHER INFORMATION CONTACT: All technical or programmatic questions concerning this announcement should be directed to Donna Ledbetter, Writer/Editor, National Institute of Corrections, who may be reached by email at *dledbetter@bop.gov.* In addition to the direct reply, all questions and responses will be posted on NIC's Web site at *www.nicic.gov* for public review (the names or affiliations of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation.

Application Requirements: Application Requirements: Applications should be typed, double spaced, in 12-point font, and reference the project by the ''NIC Opportunity Number'' (13RE3)

and title in this announcement, ''Corrections-Specific Resources for Extended Stakeholder Audiences''. The package must include: a cover letter that identifies the audit agency responsible for the applicant's financial accounts as well as the audit period or fiscal year that the applicant operates under (*e.g.,* July 1 through June 30); a concisely written program narrative, not to exceed 30 numbered pages, in response to the statement of work, and a detailed budget with a budget narrative explaining projected costs. Applicants may submit a description of the project teams' qualifications and expertise relevant to the project, but should not attach lengthy resumes. Large attachments to the proposal describing the organization or examples of other past work are discouraged.

The following forms must also be included: OMB Standard Form 424, Application for Federal Assistance; OMB Standard Form 424A, Budget information—Non-Construction Programs; OMB Standard Form 424B, Assurances—Non-Construction Programs (these forms are available at *http://www.grants.gov*) and DOJ/NIC Certification Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and the Drug-Free Workplace Requirements (available at *http://nicic.gov/Downloads/General/certif-frm.pdf).*

Failure to supply all required forms with the application package may result in disqualification of the application from consideration.

Note: NIC will NOT award a cooperative agreement to an applicant who does not have a Dun and Bradstreet Database Universal Number (DUNS) and is not registered in the Central Contractor Registry (CCR).

A DUNS number can be received at no cost by calling the dedicated toll-free DUNS number request line at 1–800–333–0505 (if you are a sole proprietor, you would dial 1–866–705–5711 and select option 1).

Registration in the CRR can be done online at the CCR Web site: *http://www.bpn.gov/ccr.* A CCR Handbook and worksheet can also be reviewed at the Web site.

Review Considerations: Applications received under this announcement will be subject to the NIC Review Process. Proposals which fail to provide sufficient information to allow evaluation under the criteria below may be judged non-responsive and disqualified.

The criteria for the evaluation of each application will be as follows:

Programmatic (40%)

Are all of the project tasks adequately discussed? Is there a clear statement of how each task will be accomplished, including major sub-tasks, the strategies to be employed, required staffing, and other required resources? Are there any innovative approaches, techniques, or design aspects proposed that will enhance the project?

Organizational (35%)

Does the proposed project staff possess the skills, knowledge, and expertise necessary to complete the tasks listed under the scope of work? Does the applicant organization, group, or individual have the organizational capacity to achieve all project tasks? Are the proposed project management and staffing plans realistic and sufficient to complete the project within the project time frame?

Project Management/Administration (25%)

Does the applicant identify reasonable objectives, milestones, and measures to track progress? If consultants and/or partnerships are proposed, is there a reasonable justification for their inclusion in the project, and a clear structure to ensure effective coordination? Is the proposed budget realistic, does it provide a sufficient cost detail/narrative, and does it represent good value relative to the anticipated results?

Specific Requirements: Documents or other media that are produced under this award must follow these guidelines: Prior to the preparation of the final draft of any document or other media, the awardee must consult with NIC's Writer/Editor concerning the acceptable formats for manuscript submissions and the technical specifications for electronic media. For all awards in which a document will be a deliverable, the awardee must follow the guidelines listed herein, as well as follow the Guidelines for Preparing and Submitting Manuscripts for Publication as found in the ''General Guidelines for Cooperative Agreements,'' which can be found on our Web site at *www.nicic.gov/cooperativeagreements.*

All final documents and other materials submitted under this project must meet the federal government's requirement for Section 508 accessibility, including those provisions outlined in 1194 Subpart B, Technical Provisions; Subpart C, Functional Performance Criteria; and Subpart D, Documentation and Support. NIC's government product accessibility template (see *www.nicic.gov/section508)* outlines the agency's minimum criteria for meeting this requirement; a completed form attesting to the accessibility of project deliverables should accompany all submissions.

Note Concerning Catalog of Federal Domestic Assistance Number: This number should be entered in section 10 of the Application for Federal Assistance (SF–424). You should enter 16.602 (Research and Policy Formulation) in section 10 of the SF–424. You are not subject to the provisions of Executive Order 12372 and should check Box b. in section 16.

Robert Brown, Jr.

Acting Director, National Institute of Corrections.

[FR Doc. 2013–13952 Filed 6–11–13; 8:45 am]

BILLING CODE 4410–36–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Curriculum Development: Planning and Implementing Effective Mental Health Services in Jails

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a Cooperative Agreement.

SUMMARY: The National Institute of Corrections (NIC) is soliciting proposals from organizations, groups, or individuals to enter into a cooperative agreement for an 18-month period to begin no later than September 15, 2013. Work under this cooperative agreement will involve developing curriculum, based on the Instructional Theory Into Practice (ITIP) model, to train participants in the purpose, functions, and operational complexities surrounding the housing and treatment issues of inmates exhibiting signs and symptoms of mental illness. The awardee will produce a program description (overview), detailed narrative lesson plans, a participant manual that follows the lesson plans, and presentation slides for each lesson plan. A qualified awardee will have expertise in developing effective mental health treatment inside of jails and extensive experience in working with local jails on issues related to inmate mental health treatment. This project will be a collaborative venture with the NIC Jails Division.

NIC Opportunity Number: 13JD02. This number should appear in the reference line in your cover letter, on Standard Form 424 in section 11 with the title of your proposal, and in the right justified header of your proposal.

Number of Awards and Funds Available: Under this solicitation, one award will be made. The total amount of funds available under this solicitation is $120,000.00. Funds awarded under this solicitation may only be used for activities directly related to the project as described herein unless otherwise amended in writing by NIC.

Applications: All applicants must be submitted electronically via *http://www.grants.gov.* Hand delivered, mailed, faxed, or emailed applications will not be accepted.

DATES: Application must be submitted before midnight on Wednesday, July 3, 2013.

Authority: Pub. L. 93–415.

Eligibility of Applicants: An eligible applicant is any public or private agency, educational institution, organization, individual or team with expertise in the described areas.

SUPPLEMENTARY INFORMATION:

Background: Local jails face significant challenges in managing inmates who are mentally ill. Often, jails do not have the trained personnel or other resources to provide adequate services to these inmates and would benefit greatly from a collaborative working relationship with the community's mental health services provider. The purpose of this curriculum is to help local jail practitioners and mental health service providers (1) understand the key elements of effective mental health services for jail inmates and (2) forge a productive working relationship that facilitates the provision of services for offenders with mental illness.

Scope of Work: The cooperative agreement awardee will draft a curriculum on (1) the key elements of effective mental health services in jails and (2) the need for and types of collaboration necessary between the jail and community mental health services. The awardee will also pilot the curriculum and revise the curriculum based on an assessment of the pilot. The schedule of activities for this project should include, at a minimum, the following:

Meetings

The cooperative agreement awardee will attend an initial meeting with the NIC project manager for a project overview and preliminary planning. This will take place shortly after the cooperative agreement is awarded.

The awardee will also conduct two meetings with NIC staff and up to five subject matter experts (SMEs) in attendance. The purpose of these meetings is to identify clearly the needs for and obstacles to implementing effective mental health services in jails. Note that the SMEs will be selected by NIC in consultation with the awardee, but all costs associated with their meeting attendance will be paid by the awardee.

The awardee will meet up to three times with NIC staff during the development of the draft curriculum. One meeting will be devoted to drafting a framework for the curriculum, including module topics, performance objectives, estimated timeframes, sequencing, and potential instructional strategies. The other meetings will focus on lesson plan development, review, and revision, and on other project issues, as they arise. These meetings will last up to 3 days each.

The awardee will meet up to two times with NIC staff during the refinement of the draft curriculum into a final product. These meetings will focus on curriculum revisions and other project issues as they arise.

The applicant should plan for all meetings to take place at the NIC office in Washington, DC. However, NIC will make provision for meetings through electronic means if unforeseen circumstances require.

Development of Draft Curriculum

The cooperative agreement awardee will draft the full curriculum in consultation with NIC staff. Once the curriculum is drafted, the awardee will send it to NIC staff and selected jail mental health professionals for review.

The jail mental health professionals will be chosen by NIC in consultation with the awardee, but the awardee will reimburse them for time and expenses related to the review. The draft curriculum must be submitted sufficiently in advance of the pilot to ensure there is time to make any required changes.

Curriculum Pilot

The draft curriculum will be piloted to determine needed refinements. Although the length of the program will be determined by the content, the awardee should project that the program will last up to 3 full days.

The awardee, in conjunction with NIC, will identify up to three trainers for the program. The awardee will contract with and pay all costs associated with the trainers, including travel, lodging, meals, fees, and miscellaneous expenses. The awardee will also furnish each trainer with a set of the approved lesson plans, participant manual, and presentation slides. NIC will select program participants; notify participants of selection and program details; supply training materials, including participant manuals; and secure, through a partnership agreement with a local jurisdiction, training space.

NIC staff will attend the entire program, and the awardee will work closely with NIC staff during program delivery. At the end of each program day, the awardee will meet with NIC staff to review the modules delivered.

Curriculum Revision and Final Product

Based on the pilot and discussions with NIC staff, the awardee will revise the curriculum. The awardee will submit the revised curriculum to NIC staff for final review and make any remaining changes. The awardee will submit the completed curriculum to NIC in hard copy and on disk.

Deliverables: The final curriculum will include a program description (overview), detailed narrative lesson plans and a participant manual that follows the lesson plans (both in Word format) and presentation slides for each lesson plan (in PowerPoint format). The curriculum will be designed according to the ITIP model for adult learners. Lesson plans will be in a format that NIC provides.

FOR FURTHER INFORMATION CONTACT: All technical or programmatic questions concerning this announcement should be directed to Mike Jackson, Correctional Program Specialist, National Institute of Corrections who may be reached by email at *mpjackson@bop.gov. In addition to the direct reply, all questions and responses will be posted on NIC's Web site at www.nicic.gov* for public review (the names or affiliations of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation.

Application Requirements: Application Requirements: Applications should be typed, double spaced, in 12-point font, and reference the project by the ''NIC Opportunity Number'' (13JD02) and title in this announcement, ''Curriculum Development: Planning and Implementing Effective Mental Health Services in Jails.'' The package must include: a cover letter that identifies the audit agency responsible for the applicant's financial accounts as well as the audit period or fiscal year that the applicant operates under (e.g., July 1 through June 30); a concisely written program narrative, not to exceed 30 numbered pages, in response to the statement of work, and a detailed budget with a budget narrative explaining projected costs. Applicants may submit a description of the project teams'

qualifications and expertise relevant to the project, but should not attach lengthy resumes. Applicants must also attach a lesson plan in ITIP format, the corresponding participant material and the presentation slides from a curriculum that they have developed as a sample for consideration. These attachments should not exceed 5MB.

The following forms must also be included: OMB Standard Form 424, Application for Federal Assistance; OMB Standard Form 424A, Budget information—Non-Construction Programs; OMB Standard Form 424B, Assurances—Non-Construction Programs (these forms are available at *http://www.grants.gov*) and DOJ/NIC Certification Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and the Drug-Free Workplace Requirements (available at *http://nicic.gov/Downloads/General/certif-frm.pdf.*

Failure to supply all required forms with the application package may result in disqualification of the application from consideration.

Note: NIC will NOT award a cooperative agreement to an applicant who does not have a Dun and Bradstreet Database Universal Number (DUNS) and is not registered in the Central Contractor Registry (CCR).

A DUNS number can be received at no cost by calling the dedicated toll-free DUNS number request line at 1–800–333–0505 (if you are a sole proprietor, you would dial 1–866–705–5711 and select option 1).

Registration in the CRR can be done online at the CCR Web site: *http://www.bpn.gov/ccr.* A CCR Handbook and worksheet can also be reviewed at the Web site.

Review Considerations: Applications received under this announcement will be subject to the NIC Review Process. Proposals which fail to provide sufficient information to allow evaluation under the criteria below may be judged non-responsive and disqualified.

The criteria for the evaluation of each application will be as follows:

Programmatic (40%)

Are all of the project tasks adequately discussed? Is there a clear statement of how each task will be accomplished, to include the overall project goal(s), major tasks to achieve the goal(s), the strategies to be employed in completing the tasks, required staffing, and other required resources? Are there any approaches, techniques, or design aspects proposed that are new to NIC and will enhance the project?

Organizational (35%)

Do the proposed project staff members possess the skills, knowledge, and expertise necessary to complete the tasks listed under the scope of work? Does the applicant organization, group, or individual have the organizational capacity to complete all project tasks? Does the proposal contain project management and staffing plans that are realistic and sufficient to complete the project within the project time frame?

Project Management/Administration (25%)

Does the applicant identify reasonable objectives and/or milestones that reflect the key tasks, and measures to track progress? If consultants and/or partnerships are proposed, is there a reasonable justification for their inclusion in the project, and a clear structure to ensure effective coordination? Is the proposed budget realistic, does it provide a sufficient cost detail/narrative, and does it represent good value relative to the anticipated results?

Specific Requirements: Documents or other media that are produced under this award must follow these guidelines: Prior to the preparation of the final draft of any document or other media, the awardee must consult with NIC's Writer/Editor concerning the acceptable formats for manuscript submissions and the technical specifications for electronic media. For all awards in which a document will be a deliverable, the awardee must follow the guidelines listed herein, as well as follow the Guidelines for Preparing and Submitting Manuscripts for Publication as found in the ''General Guidelines for Cooperative Agreements,'' which can be found on our Web site at *www.nicic.gov/cooperativeagreements.*

All final documents and other materials submitted under this project must meet the federal government's requirement for Section 508 accessibility, including those provisions outlined in 1194 Subpart B, Technical Provisions, Subpart C, Functional Performance Criteria; and Subpart D, Documentation and Support, NIC's government product accessibility template (see *www.nicic.gov/section508*) outlines the agency's minimum criteria for meeting this requirement; a completed form attesting to the accessibility of project deliverables should accompany all submissions.

Note Concerning Catalog of Federal Domestic Assistance Number: The Catalog of Federal Domestic Assistance (CFDA) should be entered into box 10 of the SF 424. The CFDA number for this solicitation is 16.601, Training and Staff Development. You are not subject to Executive Order 12372 and should check box b under section 16.

Robert M. Brown, Jr.,

Acting Director, National Institute of Corrections.

[FR Doc. 2013–13945 Filed 6–11–13; 8:45 am]

BILLING CODE 4410–36–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—IBM Instructional Guide and Assessment Tool Development

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a Cooperative Agreement.

SUMMARY: The National Institute of Corrections (NIC) is soliciting proposals from organizations, groups, or individuals to enter into a cooperative agreement for a 12-month period to begin no later than September 15, 2013. Work under this cooperative agreement will involve the development of an instructional guide and assessment tool(s) that will help jail practitioners improve their assessment of inmate needs and management of inmate behavior. Needs are defined as the physical or psychological requirement for well-being. Inmates have a variety of needs that should be identified and managed during their stay in jail. This project will be a collaborative venture with the NIC Jails Division.

NIC Opportunity Number: 13JD04. This number should appear in the reference line in your cover letter, on Standard Form 424 in section 11 with the title of your proposal, and in the right justified header of your proposal.

Number of Awards and Funds Available: Under this solicitation, one award will be made. The total amount of funds available under this solicitation is $30,000.00. Funds awarded under this solicitation may only be used for activities directly related to the project as described herein unless otherwise amended in writing by NIC.

Applications: All applicants must be submitted electronically via *http://www.grants.gov*. Hand delivered, mailed, faxed, or emailed applications will not be accepted.

DATES: Application must be submitted before midnight on Wednesday, July 3, 2013.

Authority: Pub. L. 93–415.

Eligibility of Applicants: An eligible applicant is any public or private

agency, educational institution, organization, individual or team with expertise in the described areas.

SUPPLEMENTARY INFORMATION:

Background: The National Institute of Corrections (NIC) has identified six key elements in the effective management of inmate behavior in jails:

—Assessing the risks and needs of each inmate at various points during his/her detention
—Assigning inmates to appropriate housing
—Meeting inmates' basic needs
—Defining and conveying expectations for inmate behavior
—Supervising inmates
—Keeping inmates productively occupied

If a jail fully and properly implements all six elements, it should experience a significant reduction in the unwanted and negative inmate behavior often experienced in jails, such as vandalism, violence, rule violations, and disrespectful behavior toward staff and other inmates.

The NIC Jails Division offers training and technical assistance on inmate behavior management but wishes to develop additional tools that will help jails implement the individual elements.

Scope of Work: The awardee will produce an instructional guide and assessment tool(s) that have received initial editing from a professional editor. NIC will be responsible for the final editing process, but the awardee will remain available during this time to answer questions and to make revisions to the materials.

The list below shows the major activities required to complete the project. Document development will begin upon award of this agreement and must be complete 12 months after the award date. The schedule for completion of activities should include, at a minimum, the following activities. The awardee will:

—Meet with the NIC project manager for an overview of the project and initial planning
—Review materials provided by NIC
—Review needs assessment tool(s) that are currently available
—Complete the initial outline of a guide, a draft of the tool(s) content, and layout
—Meet with the NIC project manager to review, discuss, and agree on the content outline
—Pilot test the assessment tool(s) in at least two selected jurisdictions
—Provide a report on the outcome of the pilot tests and make adjustments as necessary
—Submit a draft of the assessment tool(s) and instructional guide to NIC for review
—Revise the items for NIC's approval
—Submit the material to NIC in hard copy and on disk in an agreed upon format, e.g. Microsoft Word or Excel.

Throughout the project period, the awardee should make provision for meetings with NIC staff to be held in Washington, DC, at critical planning and review points in document development. Meetings can be accomplished using internet conferencing such as WebEx.

Jail administrators and management staff comprise the audience for these materials. This guide is intended for use by jails of all sizes. In developing the assessment tool(s) and instructional guide, the awardee must take into account the diversity of jails in terms of size and resources and the sometimes severe resource limitations many jails face.

Jail practitioners will use these tools to assess inmate needs at the time of entry to a facility and at various points during incarceration. The tool(s) will work in conjunction with the assessment of risk tools. The products will be companions to other materials NIC is developing on inmate behavior management.

Deliverables: Deliverables for this project include completed assessment tool(s) that have been professionally edited and an instructional guide for the tool(s) submitted in Word format.

FOR FURTHER INFORMATION CONTACT: All technical or programmatic questions concerning this announcement should be directed to Fran Zandi, Correctional Program Specialist, National Institute of Corrections who may be reached by email at *fzandi@bop.gov*. In addition to the direct reply, all questions and responses will be posted on NIC's Web site at *www.nicic.gov* for public review (the names or affiliations of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation.

Application Requirements: Application Requirements: Applications should be typed, double spaced, in 12-point font, and reference the project by the ''NIC Opportunity Number'' (13JD04) and title in this announcement, ''IBM Instructional Guide and Assessment Tool Development.'' The package must include: a cover letter that identifies the audit agency responsible for the applicant's financial accounts as well as the audit period or fiscal year that the applicant operates under (e.g., July 1 through June 30); a concisely written program narrative, not to exceed 30 numbered pages, in response to the statement of work, and a detailed budget with a budget narrative explaining projected costs. Applicants may submit a description of the project teams' qualifications and expertise relevant to the project, but should not attach lengthy resumes. Attachments to the proposal describing your organization or examples of other past work beyond those specifically requested above are discouraged. These attachments should not exceed 5MB. The following forms must also be included: OMB Standard Form 424, Application for Federal Assistance; OMB Standard Form 424A, Budget information—Non-Construction Programs; OMB Standard Form 424B, Assurances—Non-Construction Programs (these forms are available at *http://www.grants.gov*) and DOJ/NIC Certification Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and the Drug-Free Workplace Requirements (available at *http://nicic.gov/Downloads/General/certif-frm.pdf.*

Failure to supply all required forms with the application package may result in disqualification of the application from consideration.

Note: NIC will NOT award a cooperative agreement to an applicant who does not have a Dun and Bradstreet Database Universal Number (DUNS) and is not registered in the Central Contractor Registry (CCR). A DUNS number can be received at no cost by calling the dedicated toll-free DUNS number request line at 1–800–333–0505 (if you are a sole proprietor, you would dial 1–866–705–5711 and select option 1).

Registration in the CRR can be done online at the CCR Web site: *http://www.bpn.gov/ccr.* A CCR Handbook and worksheet can also be reviewed at the Web site.

Review Considerations: Applications received under this announcement will be subject to the NIC Review Process. Proposals which fail to provide sufficient information to allow evaluation under the criteria below may be judged non-responsive and disqualified.

The criteria for the evaluation of each application will be as follows:

Programmatic (40%)

Are all of the project tasks adequately discussed? Is there a clear statement of how each task will be accomplished to include the overall project goal(s), major tasks to achieve the goals(s), the strategies to be employed in completing the tasks, required staffing, and other required resources? Are there any approaches, techniques, or design

aspects proposed that are new to NIC and will enhance the project?

Organizational (35%)

Do the proposed project staff members possess the skills, knowledge, and expertise necessary to complete the tasks listed under the scope of work? Does the applicant organization, group, or individual have the organizational capacity to achieve all project tasks? Does the proposal contain project management and staffing plans that are realistic and sufficient to complete the project within the project time frame?

Project Management/Administration (25%)

Does the applicant identify reasonable objectives, milestones, and measures to track progress? If consultants and/or partnerships are proposed, is there a reasonable justification for their inclusion in the project, and a clear structure to ensure effective coordination? Is the proposed budget realistic, does it provide a sufficient cost detail/narrative, and does it represent good value relative to the anticipated results?

Specific Requirements: Documents or other media that are produced under this award must follow these guidelines: Prior to the preparation of the final draft of any document or other media, the awardee must consult with NIC's Writer/Editor concerning the acceptable formats for manuscript submissions and the technical specifications for electronic media. For all awards in which a document will be a deliverable, the awardee must follow the guidelines listed herein, as well as follow the Guidelines for Preparing and Submitting Manuscripts for Publication as found in the ''General Guidelines for Cooperative Agreements,'' which can be found on our Web site at *www.nicic.gov/cooperativeagreements*.

All final documents and other materials submitted under this project must meet the federal government's requirement for Section 508 accessibility, including those provisions outlined in 1194 Subpart B, Technical Provisions, Subpart C, Functional Performance Criteria; and Subpart D, Documentation and Support, NIC's government product accessibility template (see *www.nicic.gov/section508*) outlines the agency's minimum criteria for meeting this requirement; a completed form attesting to the accessibility of project deliverables should accompany all submissions.

Note Concerning Catalog of Federal Domestic Assistance Number: The Catalog of Federal Domestic Assistance (CFDA) should be entered into box 10 of the SF 424. The CFDA number for this solicitation is 16.603—Technical Assistance/Clearinghouse. You are subject to the provisions of Executive Order 12372. The order allows states the option of setting up a system for reviewing applications from within their states for assistance under certain Federal programs. You must notify the Single State Point of Contact in your state, if it exists, of this application before NIC can make an award. Applicants (other than Indian tribal governments recognized by the Federal government) should contact their State Single Point of Contact (SPOC), a list of which can be found at *http://www.whitehouse.gov/omb/grants_spoc*. Check the appropriate box in section 16 of the SF–424.

Robert M. Brown, Jr.,

Acting Director, National Institute of Corrections.

[FR Doc. 2013–13948 Filed 6–11–13; 8:45 am]

BILLING CODE 4410–36–P

DEPARTMENT OF JUSTICE

National Institute of Corrections

Solicitation for a Cooperative Agreement—Gender-Informed Research (Women): Enhanced Approaches to Project Development

AGENCY: National Institute of Corrections, U.S. Department of Justice.

ACTION: Solicitation for a Cooperative Agreement.

SUMMARY: The National Institute of Corrections (NIC) is seeking applications from organizations, groups, or individuals to enter into a cooperative agreement with NIC for an 18-month period to begin no later than September 15, 2013. Work under this cooperative agreement will involve convening a working group with the purpose of identifying key areas of gender-informed knowledge specific to women that will both inform a future research agenda and define a project that would further incorporate these keys areas into NIC initiatives and provide further guidance for policymakers and practitioners in their management of this population. The audience for this project is quite broad, representing all aspects of corrections (jails, prisons, and community corrections), the research and academic community, other Federal agencies, state and local entities and other related stakeholders that have an interest in this population. The deliverables from this solicitation will be based on research and theory and are meant to provide a medium to inform NIC initiatives as well as more generally the corrections field, with the goal of improved system and individual outcomes. This project will be a collaborative venture with the NIC Community Services Division.

NIC Opportunity Number: 13CS12 This number should appear in the reference line in your cover letter, on Standard Form 424 in section 11 with the title of your proposal, and in the right justified header of your proposal.

Number of Awards and Funds Available: Under this solicitation, 1 (one) Award will be made. The total amount of funds available under this solicitation is $65,000.00.

Applications: All applicants must be submitted electronically via *http://www.grants.gov.* Hand delivered, mailed, faxed, or emailed applications will not be accepted.

DATES: Application must be submitted before midnight on Tuesday, July 9, 2013.

Authority: Public Law 93–415.

Eligibility of Applicants: An eligible applicant is any public or private agency, educational institution, organization, individual or team with expertise in the described areas.

SUPPLEMENTARY INFORMATION:

Background: Historically, studies focusing on the management of correctional populations have drawn their inferences from samples that have been predominantly male, with hypotheses developed from those same bodies of research. Much of that research applies to both justice-involved women and men, and the incorporation of that research in correctional policy and practice has advanced the profession and contributed to the improved use of resources. However, there has been emerging research specific to justice-involved women and the most significant innovation in policy, practice, and gender-informed programs for women has occurred during the past 10 years or so.

In 2006, NIC convened a meeting of researchers and practitioners focusing on the evidence-based research that was often perceived as being equally applicable to both men and women and gender-informed research, which has been developed on samples composed entirely of women. The purpose of that event was to identify important key findings regarding gender-responsive strategies and evidence-based practices; develop consensus on areas of convergence across the bodies of knowledge; explore those beliefs and assumptions that were not yet fully supported by large bodies of research but could nonetheless guide future research and policy with justice-involved women; identify key research questions; and discuss the ways that NIC could guide the field in its work

with this population. Emanating from the 2006 meeting were areas of consensus within the bodies of research; areas identified as more salient with women than men; the importance of incorporating trauma-informed practice into supervision and treatment; use of interventions that are gender-responsive to achieve the greatest outcomes for women; and a need to clarify behaviors for women that contribute to their risk.

In the ensuing 7 years, many of the recommendations have been incorporated into NIC's initiatives with women (e.g., women's risk and need assessments and a case management model, gender-informed practice assessments for women's institutions, training programs and technical assistance) and are available for use in the corrections field.

The precepts of evidence-based practice continue to be a hallmark of good correctional practice. Other emerging areas of research are also being incorporated into correctional policy and procedure. Research on the role of identifying strengths and resiliency, sources of social capital, add to our understanding of justice-involved programming and supervision. As the United States continues to top the world's rates of incarceration, increased attention is also being given to research on decarceration, desistance, and re-entry from prison and jail settings. NIC has worked in this area for a number of years, and more recently, the Federal Interagency Reentry Council at the U.S. Department of Justice was created to further address community safety through reductions in recidivism and victimization, assisting those returning from jail and prison to the community in becoming productive citizens by addressing the financial and collateral costs of incarceration. A working group stemming from the larger federal initiative was subsequently formed, focusing on issues affecting women not unlike the ones noted above.

Other more recent contributions to improving correctional practice has been the creation of the Prison Rape Elimination Act (PREA) National Standards to Prevent, Detect, and Respond to Prison Rape, which were built upon extensive research and outreach to affected groups. This is but a small sampling of some of the changes that have been emerging over the very recent past. They call for the development of opportunities to share this information with practitioners for use in their correctional practice with justice-involved women.

Scope of Work: In full collaboration with NIC, the awardee will facilitate a planning/work session composed of researchers and practitioners with expertise in evidence-based, gender-informed research, policy, and practice. In preparation for the working session, the awardee will: identify the range of topics that will form the basis of the work of the planning group; develop a bibliography of relevant materials; identify various subject matter experts based on their skills, knowledge, and expertise and be responsible for their costs to participate in the planning/work session; designate roles and tasks that need to be accomplished by participants and convey that information prior to the onsite meeting; determine a meeting site and develop an agenda, stating clear outcomes for the meeting; provide meeting facilitation; share with all participants a record of the meeting, which will subsequently be made available on the NIC Web site; engage with NIC project staff, work session participants and other identified designated experts to develop identified deliverables.

Deliverables: Project deliverables will include (1) An annotated bibliography highlighting the emerging research applicable to the management of justice-involved women; (2) identification and an outline of a proposed initiative that will be informed by the key research noted above (e.g., elements of desistance that can be incorporated into a project contributing to improved outcomes for justice-involved women); (3) preparation of materials and (4) the conducting of a series of webinar events to highlight the key emerging research and knowledge for a broad correctional audience and relevant stakeholders.

This project will be completed in conjunction with the NIC Community Services Division and the awardee will work closely with NIC staff on all aspects of the project. The awardee will participate in an initial meeting with designated NIC staff for a project overview and preliminary planning. Additionally, the awardee will meet routinely with NIC staff to discuss the activities noted in the project timeline submitted during the course of the cooperative agreement. Meetings will be held no less than quarterly and may be conducted via webinar with at least one onsite as agreed upon by NIC and the awardee.

FOR FURTHER INFORMATION CONTACT: All technical or programmatic questions concerning this announcement should be directed to Maureen Buell, Correctional Program Specialist, National Institute of Corrections, Community Services Division who may be reached by email at *mbuell@bop.gov* In addition to the direct reply, all questions and responses will be posted on NIC's Web site at *www.nicic.gov* for public review (the names or affiliations of those submitting questions will not be posted). The Web site will be updated regularly and postings will remain on the Web site until the closing date of this cooperative agreement solicitation.

Application Requirements: Applications should be typed, double spaced, in 12-point font, and reference the project by the ''NIC Opportunity Number'' 13CS12 and title in this announcement, ''Gender-Informed Research (Women): Enhanced Approaches to Project Development.'' The package must include: a cover letter that identifies the audit agency responsible for the applicant's financial accounts as well as the audit period or fiscal year that the applicant operates under (e.g., July 1 through June 30); a concisely written program narrative, not to exceed 30 numbered pages, in response to the statement of work, and a detailed budget with a budget narrative explaining projected costs. Applicants may submit a description of the project teams' qualifications and expertise relevant to the project, but should not attach lengthy resumes. Attachments to the proposal describing your organization or examples of other past work beyond those specifically requested above are discouraged.

The following forms must also be included: OMB Standard Form 424, Application for Federal Assistance; OMB Standard Form 424A, Budget information—Non-Construction Programs; OMB Standard Form 424B, Assurances—Non-Construction Programs (these forms are available at *http://www.grants.gov*) and DOJ/NIC Certification Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters; and the Drug-Free Workplace Requirements (available at *http://nicic.gov/Downloads/General/certif-frm.pdf.*

Failure to supply all required forms with the application package may result in disqualification of the application from consideration.

Note: NIC will NOT award a cooperative agreement to an applicant who does not have a Dun and Bradstreet Database Universal Number (DUNS) and is not registered in the Central Contractor Registry (CCR).

A DUNS number can be received at no cost by calling the dedicated toll-free DUNS number request line at 1–800–333–0505 (if you are a sole proprietor, you would dial 1–866–705–5711 and select option 1). Registration in the CRR can be done online at the CCR Web site: *http://www.bpn.gov/ccr.* A CCR

Handbook and worksheet can also be reviewed at the Web site.

Review Considerations: Applications received under this announcement will be subject to the NIC Review Process. Proposals which fail to provide sufficient information to allow evaluation under the criteria below may be judged non-responsive and disqualified.

The criteria for the evaluation of each application will be as follows:

Programmatic (40%)

Are all of the project tasks adequately discussed? Is there a clear statement of how each task will be accomplished to include the overall project goal(s), major tasks to achieve the goals(s), the strategies to be employed in completing the tasks, required staffing, and other required resources? Are there any approaches, techniques, or design aspects proposed that are new to NIC and will enhance the project?

Organizational (35%)

Do the proposed project staff members possess the skills, knowledge, and expertise necessary to complete the tasks listed under the scope of work? Does the applicant organization, group, or individual have the organizational capacity to achieve all project tasks? Does the proposal contain project management and staffing plans that are realistic and sufficient to complete the project within the project time frame?

Project Management/Administration (25%)

Does the applicant identify reasonable objectives, milestones, and measures to track progress? If consultants and/or partnerships are proposed, is there a reasonable justification for their inclusion in the project, and a clear structure to ensure effective coordination? Is the proposed budget realistic, does it provide a sufficient cost detail/narrative, and does it represent good value relative to the anticipated results?

Specific Requirements: Documents or other media that are produced under this award must follow these guidelines: Prior to the preparation of the final draft of any document or other media, the awardee must consult with NIC's Writer/Editor concerning the acceptable formats for manuscript submissions and the technical specifications for electronic media. For all awards in which a document will be a deliverable, the awardee must follow the guidelines listed herein, as well as follow the Guidelines for Preparing and Submitting Manuscripts for Publication as found in the ''General Guidelines for Cooperative Agreements,'' which can be found on our Web site at *www.nicic.gov/cooperativeagreements.*

All final documents and other media submitted for posting on the NIC Web site must meet the federal government's requirement for accessibility (508 PDF or HTML file). The awardee must provide descriptive text interpreting all graphics, photos, graphs, and/or multimedia to be included with or distributed alongside the materials and must provide transcripts for all applicable audio/visual works.

Note Concerning Catalog of Federal Domestic Assistance Number: This number should be entered in section 10 of the Application for Federal Assistance (SF–424). If your application is for Training and Staff Development, enter 16.601 in section 10 of the SF–424. If your application is for Research and Policy Formulation, enter 16.602 in the section. If you have entered 16.601 or 16.602 in section 10 of the SF–424, you are not subject to the provisions of Executive Order 12372 and should check Box b. in section 16.

Robert M. Brown, Jr.,

Acting Director, National Institute of Corrections.

Required Expertise: The successful applicant, and if there are identified partner(s) will, at a minimum, have a thorough understanding of the applicable research specific to evidence-based, gender-responsive research and knowledge and can provide examples of how this knowledge has been applied to projects specific to justice-involved women; the ability to identify and access relevant research resources and organize materials into a bibliography; expertise in meeting facilitation; the ability to translate content of the working group discussion into a record of the meeting; demonstrated experience in developing and conducting remote training events; and the organizational capacity to carry out the deliverables of this project.

The narrative portion of the application should include, at a minimum, a statement indicating the applicant's understanding of the project's purpose and objectives. The applicant should state this in language that is not merely a restatement of that used in the solicitation.

Project Design and Implementation: This section should describe the design and implementation of the project and how the awardee aims to address key design and implementation issues and challenges.

Project Management: Chart of measurable project milestones and timelines must be prepared and detail the tasks necessary for the completion of each milestone.

Capabilities and Competencies: This section should describe the qualifications of the applicant organization, any partner organizations to do the work proposed, and the expertise of key staff to be involved in the project. Attach resumes that document relevant knowledge, skills, and abilities needed for each staff member assigned to complete the project. If the applicant organization has completed similar projects in the past, please include the URL/Web site or ISBN number for accessing a copy of the referenced work.

Budget: The budget should detail all costs for the project, show consideration for all contingencies for the project, note a commitment to work within the proposed budget, and demonstrate the ability to provide deliverables according to schedule.

Among the criteria used to evaluate the applications are indication of a clear understanding of the project requirements as stated in the solicitation; background, experience, and expertise of the proposed project staff, including any sub-contractors; effectiveness of an innovative approach to the project; a clear, concise description of all elements and tasks of the project, with sufficient and realistic timeframes necessary to complete the tasks; technical soundness of project design and methodology; financial and administrative integrity of the proposal, including adherence to federal financial guidelines and processes; a sufficiently detailed budget that shows consideration of all contingencies for this project and commitment to work within the proposed budget; and indication of availability to work with NIC staff.

[FR Doc. 2013–13950 Filed 6–11–13; 8:45 am]

BILLING CODE 4410–36–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prohibited Transaction Class Exemption for Certain Transactions Between Investment Companies and Employee Benefit Plans

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) revision titled, ''Prohibited Transaction Class Exemption for Certain Transactions between Investment Companies and Employee Benefit Plans,'' to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 et seq.).

DATES: Submit comments on or before July 12, 2013.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://*

www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201304-1210-009 (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503, Fax: 202–395–6881 (this is not a toll-free number), email: *OIRA_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Michel Smyth by telephone at 202–693–4129 (this is not a toll-free number) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: The prohibited transaction class exemption applicable to certain transactions between investment companies and employee benefit plans (PTE 77–4) permits an employee benefit plan to purchase and sell shares of an open-end investment company (mutual fund) when a fiduciary with respect to the plan is also the investment advisor for the mutual fund. There are three basic disclosure requirements incorporated within PTE 77–4. The first requirement is to disclose any redemption fees in the current prospectus of the open-end mutual fund. The second requirement is that, at the time of the purchase or sale of such mutual fund shares, an independent fiduciary receive a copy of the current prospectus issued by the open-end mutual fund and full written disclosure of the investment advisory fees charged to or paid by the plan and the open-end mutual fund to the investment advisor. The third requirement is that the independent fiduciary (1) be notified of any changes in the fees and (2) give written approval for the plan to purchase or sell affected mutual fund shares or the plan to continue possession of any such mutual fund shares acquired before the fee changes.

The ICR has been classified as a revision, because—pursuant to an advisory opinion request—the DOL interprets the term, *prospectus,* in PTE 77–4 to include a *summary prospectus* if the summary prospectus meets revised Securities and Exchange Commission (SEC) disclosure provisions for mutual funds, including the Summary Prospectus Rule. *See* 74 FR 4546 (January 26, 2009). Pursuant to the revised SEC disclosure provisions, mutual funds also are required to send the full prospectus to the investor upon an investor's request and to provide the full prospectus on-line at a specified internet site. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on February 14, 2013 (78 FR 10638).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0049. Existing information collection requirements submitted to the OMB will continue to apply while the ICR undergoes review. Revisions would only take effect under the PRA upon OMB authorization.

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within 30 days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210–0049. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Agency: DOL–EBSA.

Title of Collection: Prohibited Transaction Class Exemption for Certain Transactions between Investment Companies and Employee Benefit Plans.

OMB Control Number: 1210–0049.

Affected Public: Private Sector—businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 700.

Total Estimated Number of Responses: 399,300.

Total Estimated Annual Burden Hours: 33,640.

Total Estimated Annual Other Costs Burden: $219,000.

Dated: June 5, 2013.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2013–13830 Filed 6–11–13; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Division of Longshore and Harbor Workers' Compensation; Proposed Extension of Existing Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506©(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation (OWCP) is soliciting comments concerning the proposed collection: Securing Financial Obligations under the Longshore and Harbor Workers' Compensation Act and its Extension (LS–276, LS–275–IC and LS–275–SI) A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before August 12, 2013.

ADDRESSES: Mr. Vincent Alvarez, U.S. Department of Labor, 200 Constitution

Ave. NW., Room S–32331, Washington, DC 20210, telephone (202) 693–0372, fax (202) 693–1447, Email *alvarez.vincent@dol.gov.* Please use only one method of transmission for comments (mail, fax, or Email).

SUPPLEMENTARY INFORMATION:

I. Background: The Longshore and Harbor Workers' Compensation Act (LHWCA) requires covered employers to secure the payment of compensation under the Act and its extensions by purchasing insurance from a carrier authorized by the Secretary of Labor to write Longshore Act Insurance, or by becoming authorized self-insured employers (33 U.S.C. 932 et seq). Each authorized insurance carrier (or carrier seeking authorization) is required to establish annually that its Longshore obligations are fully secured either through an applicable state guaranty (or analogous) fund, a deposit of security with the Division of Longshore and Harbor Workers' Compensation (DLHWC), or a combination of both. Similarly, each authorized self-insurer (or employer seeking authorization) is required to fully secure its Longshore Act obligations by depositing security with DLHWC. These requirements are designed to assure the prompt and continued payment of compensation and other benefits by the responsible carrier or self-insurer to injured workers and their survivors. Forms LS–276, Application for Security Deposit Determination; LS–275–IC, Agreement and Undertaking (Insurance Carrier); and LS–275–SI, Agreement and Undertaking (Self-insured Employer) are used to cover the submission of information by insurance carriers and self-insured employers regarding their ability to meet their financial obligations under the Longshore Act and its extensions. This information collection is currently approved for use through November 30, 2013.

II. Review Focus: The Department of Labor is particularly interested in comments which:

* evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

* evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* enhance the quality, utility and clarity of the information to be collected; and

* minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions: The Department of Labor seeks the approval for the extension of this currently-approved information collection in order to carry out its responsibility to ensure that a carrier's LHWCA obligations are sufficiently secured and, if necessary, to deposit security in an amount set by OWCP. This procedure will ensure the prompt and continued payments of compensation and medical benefits to injured workers and help protect the Longshore special funds assets from consequences flowing from insurance carriers' insolvencies.

Type of Review: Extension.

Agency: Office of Workers' Compensation Programs.

Title: Request for Earnings Information.

OMB Number: 1240–0005.

Agency Number: LS–276, LS–275–IC and LS–275–SI.

Affected Public: Business or other for-profit, Not-for-profit institution.

Total Respondents: 569.

Total Annual Responses: 668.

Estimated Total Burden Hours: 454.

Estimated Time per Response: 15 minutes to 60 minutes.

Frequency: Annually.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $344.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: June 6, 2013.

Vincent Alvarez,

Agency Clearance Officer, Office of Workers' Compensation Programs, U.S. Department of Labor.

[FR Doc. 2013–13957 Filed 6–11–13; 8:45 am]

BILLING CODE 4510–CF–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Division of Coal Mine Workers' Compensation; Proposed Collection of Existing Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation Programs is soliciting comments concerning the proposed collection: Request for State or Federal Workers' Compensation Information (CM–905). A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section below on or before August 12, 2013.

ADDRESSES: Mr. Vincent Alvarez, U.S. Department of Labor, 200 Constitution Ave. NW., Room S–32331, Washington, DC 20210, telephone (202) 693–0372, fax (202) 693–1447, Email *alvarez.vincent@dol.gov.* Please use only one method of transmission for comments (mail, fax, or Email).

SUPPLEMENTARY INFORMATION

I. Background: The Federal Mine Safety and Health Act of 1977, as amended (30 U.S.C. 901) and 20 CFR 725.535, require that DOL Black Lung benefit payments to a beneficiary for any month be reduced by any other payments of state or federal benefits for workers' compensation due to pneumoconiosis. To ensure compliance with this mandate, DCMWC must collect information regarding the status of any state or Federal workers' compensation claim, including dates of payments, weekly or lump sum amounts paid, and other fees or expenses paid out for this award, such as attorney fees and related expenses associated with pneumoconiosis. Form CM–905 is used to request the amount of those workers' compensation benefits. This information collection is currently approved for use through October 31, 2013.

II. Review Focus: The Department of Labor is particularly interested in comments which:

* evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including

whether the information will have practical utility;

* evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

* enhance the quality, utility and clarity of the information to be collected; and

* minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

III. Current Actions: The Department of Labor seeks the approval for the extension of this currently-approved information collection in order to gather information to determine the amounts of Black Lung benefits paid to beneficiaries. Black Lung amounts are reduced dollar for dollar, for other Black Lung related workers' compensation awards the beneficiary may be receiving from State or Federal programs.

Type of Review: Extension.

Agency: Office of Workers' Compensation Programs.

Title: Request for State or Federal Workers' Compensation Information.

OMB Number: 1240–0032.

Agency Number: CM–905.

Affected Public: Federal government; State, Local or Tribal Government.

Total Respondents: 2000.

*Total Annual Respon*ses: 2000.

Average Time per Response: 15 minutes.

Estimated Total Burden Hours: 500.

Frequency: On occasion.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $980.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: June 6, 2013.

Vincent Alvarez,

Agency Clearance Officer, Office of Workers' Compensation Programs, US Department of Labor.

[FR Doc. 2013–13953 Filed 6–11–13; 8:45 am]

BILLING CODE 4510–CK–P

NATIONAL MEDIATION BOARD

Notice of Proposed Information Collection Requests

AGENCY: National Mediation Board.

SUMMARY: The Director, Office of Administration, invites comments on the proposed information collection requests as required by the Paperwork Reduction Act of 1995.

DATES: Interested persons are invited to submit comments within 60 days from the date of this publication.

SUPPLEMENTARY INFORMATION: Section 3506 of the Paperwork Reduction Act of 1995 (U.S.C. Chapter 35) requires that the Office of Management and Budget (OMB) provide interested Federal agencies and the public an early opportunity to comment on information collection requests. OMB may amend or waive the requirement for public consultation to the extent that public participation in the approval process would defeat the purpose of the information collection, violate State or Federal law, or substantially interfere with any agency's ability to perform its statutory obligations. The Chief Information Officer, Finance and Administration Department, publishes that notice containing proposed information collection requests prior to submission of these requests to OMB. Each proposed information collection contains the following: (1) Type of review requested, e.g. new, revision extension, existing or reinstatement; (2) Title; (3) Summary of the collection; (4) Description of the need for, and proposed use of, the information; (5) Respondents and frequency of collection; and (6) Reporting and/or Record keeping burden. OMB invites public comment.

Currently, the National Mediation Board is soliciting comments concerning the new collection of information in the form of Request for Arbitration Panel for Airline System Boards of Adjustment, Request for Public Law Board Member, Arbitration Services-Personal Data Sheet and is interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the agency; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the agency enhance the quality, utility, and clarity of the information to be collected; and (5) how might the agency minimize the burden of this collection on the respondents, including through the use of information technology.

Dated: June 6, 2013.

June D.W. King,

Director, Office of Administration, National Mediation Board.

A. Request for Arbitration Panel for Airline System Boards of Adjustment

Type of Review: New Collection.

Title: Request for Arbitration Panel for Airlines System Boards of Adjustment.

Frequency: On occasion.

Affected Public: Airline Carrier and Union Officials.

Reporting and Recordkeeping Hour Burden:

Responses: Estimate about 80 annually.

Burden Hours: 20.

Abstract: Section 183 of the Railway Labor Act, 45 U.S.C., 183, provides that the parties to the labor-management disputes in the airline industry must have a procedure for the resolution of disputes involving the interpretation or application of provisions of the collective bargaining agreement. The Railway Labor Act mentions system board of adjustment or arbitration boards as the mechanism for resolution and is silent as to how the neutral arbitrator is to be selected if the parties are unable to agree on an individual. The National Mediation Board provides panels of arbitrators to help the parties in their selection of an arbitrator.

This form is necessary to assist the parties in this process. The parties invoke the process through the submission of this form. The brief information is necessary for the NMB to perform this important function.

B. Request for Public Law Board Member

Type of Review: New Collection.

Title: Request for Public Law Board Member.

Frequency: On occasion.

Affected Public: Carrier and Union Officials of railroads.

Reporting and Recordkeeping Hour Burden:

Responses: Estimate 15 annually.

Burden Hours: 3.75.

Abstract: Section 153, Second, of the Railway Labor Act, 45 U.S.C. 153, Second, governs procedures to be followed by carriers and representatives of employees in the establishment and functioning of special adjustment boards. These special adjustment boards are referred to as public law boards (board). The statute provides that within thirty (30) days from the date a written request is made by an employee representative or carrier official for the establishment of a board, an agreement establishing such board shall be made. If, however, one party fails to designate

a member of the board, the party making the request may ask the NMB to designate a member on behalf of the other party. The NMB must designate the representative who, together with the other party constitutes the public board. It will be the task of these two individuals to decide on the terms of the agreement. If these individuals are unable to decide upon the terms, the Railway Labor Act provides that one of these parties may request that the NMB designate a neutral to resolve the remaining matters which are procedural issues. Pursuant to 29 C.F.R. 1207.2, requests for the NMB to appoint either representatives or neutrals must be made on printed forms which may be secured from the NMB.

This form is necessary for the NMB to fulfill its statutory responsibilities. Without this information, the NMB would not be able to assist the railroad labor and management representatives in resolving disputes, which is contrary to the intent of the Railway Labor Act.

C. Arbitration Services—Personal Data Sheet

Type of Review: New Collection.

Title: Arbitration Services—Personal Data Sheet.

Frequency: On occasion.

Affected Public: Arbitrators.

Reporting and Recordkeeping Hour Burden:

Responses: 25 annually.

Burden Hours: 25.

Abstract: Sections 183 and 153 of the Railway Labor Act, 45 U.S.C., 153 and 183, provide for the use of arbitrators in the resolution of disputes concerning the application or interpretation of provisions of a collective bargaining agreement in the airline and railroad industries. The NMB maintains a roster of arbitrators for this purpose. The NMB must have a means for interested individuals to apply for inclusion on this roster. This form is the application for inclusion on the NMB roster. The brief information that the NMB solicits is necessary to perform this responsibility under the Railway Labor Act.

Requests for copies of the proposed information collection request may be accessed from *www.nmb.gov* or should be addressed to Roland Watkins, Director of Arbitration Services NMB, 1301 K Street NW., Suite 250 E, Washington, DC 20005 or addressed to the email address *arb@nmb.gov* or faxed to 202–692–5086. Please specify the complete title of the information collection when making your request.

Comments regarding burden and/or the collection activity requirements should be directed to June D.W. King at 202–692–5010 or via internet address *king@nmb.gov* Individuals who use a telecommunications device for the deaf (TDD/TDY) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

[FR Doc. 2013–13872 Filed 6–11–13; 8:45 am]

BILLING CODE 7550–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. NRC–2013–0112]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of pending NRC action to submit an information collection request to the Office of Management and Budget (OMB) and solicitation of public comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) invites public comment about our intention to request OMB's approval for renewal of an existing information collection that is summarized below. We are required to publish this notice in the **Federal Register** under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

Information pertaining to the requirement to be submitted:

1. *The title of the information collection:* 10 CFR Part 11, Criteria and Procedures for Determining Eligibility for Access to or Control Over Special Nuclear Material.

2. *Current OMB approval number:* 3150–0062.

3. *How often the collection is required:* On occasion.

4. *Who is required or asked to report:* Employees (including applicants for employment), contractors, and consultants of NRC licensees and contractors whose activities involve access to, or control over, special nuclear material at either fixed sites or for transportation activities.

5. *The number of annual respondents:* 2.

6. *The number of hours needed annually to complete the requirement or request:* 82.

7. *Abstract:* The NRC regulations in Part 11 of Title 10 of the *Code of Federal Regulations* (10 CFR), establish requirements for access to special nuclear material, and the criteria and procedures for resolving questions concerning the eligibility of individuals to receive special nuclear material access authorization.

Submit, by August 12, 2013, comments that address the following questions:

1. Is the proposed collection of information necessary for the NRC to properly perform its functions? Does the information have practical utility?

2. Is the burden estimate accurate?

3. Is there a way to enhance the quality, utility, and clarity of the information to be collected?

4. How can the burden of the information collection be minimized, including the use of automated collection techniques or other forms of information technology?

The public may examine and have copied for a fee publicly available documents, including the draft supporting statement, at the NRC's Public Document Room, Room O–1F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. The OMB clearance requests are available at the NRC's Web site: *http://www.nrc.gov/public-involve/doc-comment/omb/.*

The document will be available on the NRC home page site for 60 days after the signature date of this notice. Comments submitted in writing or in electronic form will be made available for public inspection. Because your comments will not be edited to remove any identifying or contact information, the NRC cautions you against including any information in your submission that you do not want to be publicly disclosed. Comments submitted should reference Docket No. NRC–2013–0112.

You may submit your comments by any of the following methods: Electronic comments: Go to *http://www.regulations.gov* and search for Docket No. NRC–2013–0112. Mail comments to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001. Questions about the information collection requirements may be directed to the NRC Clearance Officer, Tremaine Donnell (T–5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6258, or by email to *INFOCOLLECTS.Resource@NRC.GOV.*

Dated at Rockville, Maryland, this 5th day of June 2013.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of Information Services.

[FR Doc. 2013–13856 Filed 6–11–13; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0293]

Initial Test Programs for Water-Cooled Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing a revision to Regulatory Guide (RG), 1.68, ''Initial Test Programs for Water-Cooled Nuclear Power Plants.'' This guide describes the general scope and depth that the staff of the NRC considers acceptable for Initial Test Programs (ITPs) for light water cooled nuclear power plants.

ADDRESSES: Please refer to Docket ID NRC–2012–0293 about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and are publically available, by using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0293. Address questions about NRC dockets to Carol Gallagher; telephone: 301–492–3668; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual(s) listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the NRC Library at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced in this notice is provided the first time that a document is referenced. Revision 4 of Regulatory Guide 1.68, is available in ADAMS under Accession No. ML13051A027. The regulatory analysis may be found in ADAMS under Accession No. ML13051A035.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Mark Orr, Office of Nuclear Regulatory Research, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–251–7495 or email: *mark.orr@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is issuing a revision to an existing guide in the NRC's ''Regulatory Guide'' series. This series was developed to describe and make available to the public information such as methods that are acceptable to the NRC staff for implementing specific parts of the NRC's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses. This regulatory guide is a rule as designated in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget (OMB) has not found it to be a major rule as designated in the Congressional Review Act.

II. Further Information

This guide describes the general scope and depth that the NRC staff considers acceptable for ITPs for light water cooled nuclear power plants. This RG is being revised to address design qualification tests for new design certifications (DCs) and combined licenses (COLs) using the requirements in part 52 of Title 10 of the *Code of Federal Regulations* (10 CFR), ''Licenses, Certifications, and Approvals for Nuclear Power Plants.'' This RG is also being revised to add some preoperational, low-power and power ascension tests for new light water reactors (LWRs) licensed under 10 CFR Part 52. In addition, this RG is being revised to add new and updated references.

The RG has 3 appendices. Appendix A addresses the specific tests recommended or required for the ITPs. Appendix B provides information about ITP-related inspections that the NRC staff will perform, including the appropriate regional office staff. Finally, Appendix C contains guidance on the preparation and content of procedures for preoperational, fuel loading, initial criticality, low power, and power ascension tests.

III. Backfitting and Issue Finality

Issuance of this final regulatory guide does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in 10 CFR Part 52. As discussed in the ''Implementation'' section of this regulatory guide, the NRC has no current intention to impose this regulatory guide on holders of current operating licenses or combined licenses.

This regulatory guide may be applied to applications for operating licenses and combined licenses docketed by the NRC as of the date of issuance of the final regulatory guide, as well as future applications for operating licenses and combined licenses submitted after the issuance of the regulatory guide. Such action does not constitute backfitting as defined in 10 CRF 50.109(a)(1) or is otherwise inconsistent with the applicable issue finality provision in 10 CFR Part 52, inasmuch as such applicants or potential applicants are not within the scope of entities protected by the Backfit Rule or the relevant issue finality provisions in Part 52.

Dated at Rockville, Maryland, this 31st day of May, 2013.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guide Development Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2013–13951 Filed 6–11–13; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69707]

Order Granting a Limited Exemption from Rule 102 of Regulation M Concerning the NYSE Arca, Inc.'s Exchange Traded Product Incentive Program Pilot Pursuant to Regulation M Rule 102(e)

June 6, 2013.

The Securities and Exchange Commission (''Commission'') approved a proposed rule change of the NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') to add new NYSE Arca Equities Rule 8.800 (''New Rule 8.800'') which establishes the exchange-traded product (''ETP'') Incentive Program (''Incentive Program'' or ''Program'') effective on one year on a pilot basis. The Incentive Program is designed to incentivize market makers to take Lead Market Maker (''LMM'') assignments in certain lower volume ETPs by offering an alternative fee structure for such LMMs that would be funded from the Exchange's general revenues. The costs of the Incentive Program would be funded by charging participating issuers (which may be paid by sponsors on behalf of the issuer) non-refundable ''Optional Incentive Fees,'' which would be credited to LMMs from the

Exchange's general revenues.[1] The Commission believes that payment of the Optional Incentive Fee by the issuer (or a sponsor on behalf of the issuer) for the purpose of incentivizing market makers to become LMMs in the issuer's securities would constitute an indirect attempt by the issuer to induce a bid for or a purchase of a covered security during a restricted period.[2] As a result, absent exemptive relief, participation in the Incentive Program by an issuer (or sponsor on behalf of the issuer) would violate Rule 102 of Regulation M.[3] This order grants a limited exemption from Rule 102 of Regulation M solely to permit issuers and sponsors to participate in the Program during the pilot, subject to certain conditions described below.

NYSE Arca stated that the Incentive Program is designed to incentivize market makers to undertake LMM assignments in ETPs.[4] An issuer of an ETP that participates in the Incentive Program would elect to pay an ''Optional Incentive Fee'' to NYSE Arca in an amount ranging from $10,000 to $40,000 per year with the actual amount to be determined by the issuer.[5] The Optional Incentive Fee is in addition to the currently applicable listing and annual fees applicable to the ETP and is paid by the issuer to the Exchange's general revenues.[6] Subject to the requirements set forth in New Rule 8.800, a market maker accepting an LMM assignment in an ETP in the Incentive Program would receive a payment quarterly from NYSE Arca (''LMM Payment'') in an amount equal to the Optional Incentive Fee, less a 5% NYSE Arca administration fee.[7] If the LMM does not meet or exceed its Incentive Program performance standards for an assigned ETP for a particular month or if the ETP is withdrawn from the Program pursuant to the rule, the LMM would not receive a LMM Payment for that month.[8] The voluntary Program established by New Rule 8.800 will be effective for one year on a pilot basis.[9]

Under New Rule 8.800, NYSE Arca will be required to provide notification on its Web site regarding: (i) The ETPs participating in the Incentive Program, (ii) the date a particular ETP begins participating in the Incentive Program, (iii) the date the Exchange receives written notice of an issuer's intent to withdraw its ETP from the Incentive Program, and the intended withdrawal date, if provided, (iv) the date a particular ETP ceases participating in the Incentive Program, (v) the LMM assigned to each ETP participating in the Incentive Program, (vi) the date the Exchange receives written notice of an LMM's intent to withdraw from its ETP assignment(s) in the Incentive Program, and the intended withdrawal date, if provided, and (vii) the amount of the Optional Incentive Fee for each ETP.[10] This page would also include a fair and balanced description of the Incentive Program, including (i) a description of the Incentive Program's operation as a pilot, including the effective date thereof, (ii) the potential benefits that may be realized by an ETP's participation in the Incentive Program, (iii) the potential risks that may be attendant with an ETP's participation in the Incentive Program, (iv) the potential impact resulting from an ETP's entry into and exit from the Incentive Program, and (v) how interested parties can request additional information regarding the Incentive Program and/or the ETPs participating therein.[11] Furthermore, an issuer that is approved to participate in the Incentive Program shall issue a press release to the public, in a form and manner prescribed by the Exchange, when it commences participation or ceases to participate in the Incentive Program.[12] Such press release would be issued, if practicable, at least two days before the ETP commences or ceases participation in the Incentive Program.[13] The issuer also will be required to dedicate space on its Web site, or, if it does not have a Web site, on the Web site of the adviser or sponsor of the ETP, to (i) include any such press releases and (ii) provide a hyperlink to the dedicated page on NYSE Arca's Web site that describes the Program.[14]

The Approval Order notes commenters' general support of the Program's stated goal to increase liquidity and promote efficient robust markets for ETPs.[15] However, certain commenters expressed concerns about the Program as originally proposed last year,[16] including the departure from rules precluding market makers from directly or indirectly accepting payment from an issuer of a security for acting as a market maker.[17] In particular,

[1] *See* Securities Exchange Act Release No. 69706 (June 6, 2013) (''Approval Order''). The Approval Order contains a detailed description of the Program. On March 21, 2013, the Exchange filed with the Commission, pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934, as amended (''Act'' or ''Exchange Act'') and Rule 19b–4 thereunder, a proposed rule change to establish the Program. The proposed rule change, as modified by Amendment No. 1 thereto, was published for comment in the **Federal Register** on April 11, 2013. Securities Exchange Act Release No. 69335 (Apr. 5, 2013), 78 FR 21681 (Apr. 11, 2013). The Approval Order grants approval of the proposed rule change, as modified by Amendments No. 1 and 2.

Previously, the Exchange filed, but later withdrew, an initial proposed rule change to establish the Program. On April 27, 2012, NYSE Arca filed with the Commission, pursuant to Section 19(b)(1) of the Exchange Act and Rule 19b–4 thereunder, a proposed rule change to establish the Program. The proposed rule change was published for comment in the **Federal Register** on May 17, 2012. Securities Exchange Act Release No. 66966 (May 11, 2012), 77 FR 29419 (May 17, 2012). On June 20, 2012, the Commission extended the time period in which to either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change to August 15, 2012. Securities Exchange Act Release No. 67222 (June 20, 2012), 77 FR 38116 (June 26, 2012). On July 11, 2012, the Commission instituted proceedings to determine whether to approve or disapprove the proposed rule change. Securities Exchange Act Release No. 67411 (July 11, 2012), 77 FR 42052 (July 17, 2012). On October 2, 2012, the Commission issued a notice of designation of a longer period for Commission action on proceedings to determine whether to disapprove the proposed rule change. Securities Exchange Act Release No. 67962 (Oct. 2, 2012), 77 FR 61462 (Oct. 9, 2012). On January 9, 2013, the Exchange withdrew the proposed rule change. Securities Exchange Release No. 68616 (Jan. 10, 2013), 78 FR 3482 (Jan. 16, 2013).

[2] *See* Securities Exchange Act Release No. 67411 (July 11, 2012), 77 FR 42052 (July 17, 2012) (stating ''[t]he Commission believes that issuer payments made under the SRO Proposals would constitute an indirect attempt by the issuer of a covered security to induce a purchase or bid in a covered security during a restricted period in violation of Rule 102 . . . [u]nder the NYSE Arca Proposal, the purpose of the Program is 'to create a Incentive Program for issuers of certain ETPs listed' on NYSE Arca, which . . . could induce bids or purchases for the issuer's security during a restricted period'').

[3] 17 CFR 242.102.

[4] *See* Approval Order.

[5] *Id.*

[6] *Id.* Under the current fee schedule for listings, an issuer of an ETP is required to pay a listing fee that ranges from $5,000 to $45,000. ETP issuers also pay a graduated annual fee based on the number of shares of the ETP that are outstanding, which ranges $5,000 to $55,000. *See* Securities Exchange Act Release No. 67411 (July 11, 2012), 77 FR 42052 (July 17, 2012).

[7] Approval Order.

[8] *Id.*

[9] Preamble to New Rule 8.800.

[10] New Rule 8.800(b)(6).

[11] *Id.*

[12] New Rule 8.800(b)(7).

[13] *Id.*

[14] *Id.*

[15] *See* Approval Order Section II.

[16] *See* note 1, *supra.* Only two comments were received when the proposal was re-filed with the Commission, both of which were in favor of the proposal. *See* Letter from John Hyland, CFA, Chief Investment Officer, United States Commodity Funds, dated April 10, 2013 and Letter from Stanislav Dolgopolov, Assistant Adjunct Professor and Lowell Milken Institute Law Teaching Fellow, University of California, Los Angeles, dated April 26, 2013. The Commission believes, however, that the concerns raised by commenters regarding the original proposal still are relevant to the proposal as re-filed with the Commission.

[17] *See, e.g.,* Letter from Gus Sauter, Managing Director and Chief Investment Officer, Vanguard, dated June 7, 2012 (citing to his comment letter regarding the similar NASDAQ Market Quality Program that included a discussion of NASD Notice

Continued

commenters to that proposal discussed the potential distortive impact on the natural market forces of supply and demand.[18] Commenters also discussed what they viewed as the failure of the originally-proposed Program requirements to adequately mitigate potential negative impacts of that proposal.[19]

One commenter stated that ''[i]ssuer payments to market makers have the potential to distort market forces, resulting in spreads and prices that do not reflect actual supply and demand.'' [20] One commenter questioned whether any safeguards could alleviate their concerns regarding issuer payments to market makers.[21] Another commenter questioned whether information relating to the similar NASDAQ Market Quality Program posted to that exchange's Web site in a similar manner as required in New Rule 8.800(b)(6) by NYSE Arca would adequately address investor protection and market integrity concerns because investors may not search an exchange Web site for important information about a particular ETP.[22]

Rule 102 of Regulation M

Rule 102 of Regulation M prohibits issuers, selling security holders, or any affiliated purchaser of such persons, directly or indirectly, from bidding for, purchasing, or attempting to induce any person to bid for or purchase a covered security [23] during the applicable restricted period in connection with a distribution of securities effected by or on behalf of an issuer or selling security holder, except as specifically permitted in the rule.[24] As mentioned above, the Commission believes that the payment of the Optional Incentive Fee would constitute an indirect attempt to induce a bid for or purchase of a covered security during the applicable restricted period.[25] As a result, absent exemptive relief, participation in the Program by a sponsor or issuer would violate Rule 102.

On the basis of the conditions set out below and the requirements set forth in New Rule 8.800, which in general are designed to help inform investors about the potential impact of the Program, the Commission finds that it is appropriate in the public interest, and is consistent with the protection of investors, to grant a limited exemption from Rule 102 of Regulation M solely to permit the payment of the Optional Incentive Fee as set forth in New Rule 8.800 during the pilot.[26] This limited exemption is conditioned on a requirement that the security participating in the Program is an ETP and the secondary market price for shares of the ETP must not vary substantially from the net asset value of such ETP shares during the duration of the ETP's participation in the Program. This condition is designed to limit the Program to ETPs that have a pricing mechanism that is expected to keep the price of the ETP shares tracking the net asset value of the ETP shares, which should make the shares less susceptible to price manipulation.

This limited exemption is further conditioned on disclosure requirements, as set forth below, which are designed to alert potential investors that the trading market for the otherwise less liquid securities in the Program may be affected by participation in the Program. By making it easier for investors to be able to distinguish which quotations may have been influenced by the Optional Incentive Fee from those that have not, and by requiring the issuers and sponsors to provide information on the potential effect of Program participation on the price and liquidity of a security participating in the Program, the required enhanced disclosure requirements are designed to inform potential investors about the potential distortive impact of the Optional Incentive Fee on the natural market forces of supply and demand. The general disclosures required by New Rule 8.800, while helpful, may not be sufficient to obtain this result.[27] The required enhanced disclosures are expected to promote greater investor protection by helping to ensure that investors will have easier access to important information about a particular ETP.[28]

As a practical matter, these requirements are not intended to be duplicative with the issuer disclosures required by New Rule 8.800. These requirements can be satisfied via the press release and dedicated Web page required by New Rule 8.800(b)(7), however these materials must contain all the required disclosures outlined below, and be in the manner stated in the condition, in addition to any requirements of the Exchange. Issuers or sponsors of products that are not registered under the Investment Company Act of 1940, as amended, (''1940 Act'') may also meet the press release requirements of these enhanced disclosures in a manner compliant with Regulation FD (other than Web site only disclosure).[29] We also note that, to the extent that information about participation in the Program is material, disclosure of this kind may already be

to Members 75–16 regarding the reasons for prohibiting issuer payments for market making: ''The additional factor of payments by an issuer to a market maker would probably be viewed as a conflict of interest since it would undoubtedly influence, to some degree, a firm's decision to make a market and thereafter, perhaps, the prices it would quote. Hence, what might appear to be independent trading activity may well be illusory.''). In addition, another commenter noted ''that market maker incentive programs, such as the [then-proposed Program], represent a departure from the current rules precluding market makers from accepting payment from an issuer of a security for acting as a market marker'' yet supported the concept of market maker incentive programs on a pilot basis. Letter from Ari Burstein, Investment Company Institute (''ICI''), dated June 7, 2012. In a subsequent letter, however, the same commenter noted that certain of its members opposed the Program as originally proposed and stated that it ''could create a 'pay-to-play' environment.'' Letter from Ari Burstein, ICI, dated Aug. 16, 2012. The Approval Order also notes that a number of aspects of the Program mitigate the concerns that the rule in question, FINRA Rule 5250 (Payments for Market Making), were designed to address.

[18] *See, e.g.,* Letter from F. William McNabb, Chairman and Chief Executive Officer, Vanguard, dated Aug. 16, 2012.

[19] *See, e.g.,* Letter from Gus Sauter, Managing Director and Chief Investment Officer, Vanguard, dated June 7, 2012.

[20] Letter from F. William McNabb, Chairman and Chief Executive Officer, Vanguard, dated Aug. 16, 2012.

[21] Letter from Ari Burstein, ICI, dated Aug. 16, 2012 (stating ''ICI members who oppose the Programs believe any fixes to the proposed parameters will be insufficient to address their overall concerns with market maker incentive programs'').

[22] Letter from Gus Sauter, Managing Director and Chief Investment Officer, Vanguard, dated (May 3, 2012) (asking ''[f]or example, given what we know about investor behavior, is it likely that investors would consult Nasdaq's Web site for information about which ETFs and market makers are participating in the [NASDAQ Market Quality Program] . . . [i]f not, then most investors would not be able to distinguish quotations that reflect true market forces from quotations that have been influenced by issuer payments'').

[23] Covered security is defined as any security that is the subject of a distribution, or any reference security. 17 CFR 242.100(b).

[24] 17 CFR 242.102(a).

[25] *See* note 2, *supra.*

[26] Rule 102(e) allows the Commission to grant an exemption from the provision of Rule 102, either unconditionally or on specified terms and conditions, to any transaction or class of transactions, or to any security or class of securities.

[27] New Rule 8.800(b)(7) does not contain any specific content requirements for issuer or sponsor disclosure, other than a ''press release'' when entering or leaving the Program and a hyperlink on a dedicated issuer, advisor, or sponsor's Web page to the Exchange's Web site that contains a number of specific disclosures about the program. As outlined below, the enhanced disclosures required of the issuer or sponsor as conditions to this order require that the issuer or sponsor's press release and Web page directly contain a number of helpful disclosures for investors, including risks of the program.

[28] The required Web site and press release disclosures should be less burdensome than other methods of notifying investors of a security's participation in the Program, such as requiring a ticker symbol identifier or flagging participating LMM quotes and trades.

[29] *See* condition (4), *infra.*

required by the federal securities laws and rules.

Conclusion

It is therefore ordered, that issuers or sponsors who pay an Optional Incentive Fee are hereby exempted from Rule 102 of Regulation M solely to permit the payment of the Optional Incentive Fee as set forth in New Rule 8.800 in connection with a security participating in the Program during the pilot, subject to the conditions contained in this order and compliance with the requirements of New Rule 8.800.

This exemption is subject to the following conditions:

1. The security participating in the Program is an ETP and the secondary market price for shares of the ETP must not vary substantially from the net asset value of such ETP shares during the duration of the security's participation in the Program;

2. The issuer of the participating ETP, or sponsor on behalf of the issuer, must provide prompt notice to the public by broadly disseminating a press release prior to entry (or upon re-entry) into the Program. This press release must disclose:

a. The payment of an Optional Incentive Fee is intended to generate more quotes and trading than might otherwise exist absent this payment, and that the security leaving the Program may adversely impact a purchaser's subsequent sale of the security; and

b. A hyperlink to the Web page described in condition (5) below;

3. The issuer of the participating ETP, or sponsor on behalf of the issuer, must provide prompt notice to the public by broadly disseminating a press release prior to a security leaving the Program for any reason, including termination of the Program. This press release must disclose:

a. The date that the security is leaving the Program and that leaving the Program may have a negative impact on the price and liquidity of the security which could adversely impact a purchaser's subsequent sale of the security; and

b. A hyperlink to the Web page described in condition (5) below;

4. In place of the press releases required by conditions (2) and (3) above, an issuer of a participating ETP that is not registered under the 1940 Act, or sponsor on behalf of the issuer, may provide prompt notice to the public through the use of such other written Regulation FD compliant methods (other than Web site disclosure only) that is designed to provide broad public dissemination as provided in 17 CFR 243.101(e) *provided, however,* that such other methods must contain all the information required to be disclosed by conditions (2) and (3) above;

5. The issuer of the participating ETP, or sponsor on behalf of the issuer, must provide prompt, prominent and continuous disclosure on its Web site in the location generally used to communicate information to investors about a particular security participating in the Program, and for a security that has a separate Web site, the security's Web site of:

a. The security participating in the Program and ticker, date of entry into the Program, and the amount of the Optional Incentive Fee;

b. Risk factors investors should consider when making an investment decision, including that participation in the Program may have potential impacts on the price and liquidity of the security; and

c. Termination date of the pilot, anticipated date (if any) of the security leaving the Program for any reason, date of actual exit (if applicable), and that the security leaving the Program could adversely impact a purchaser's subsequent sale of the security; and

6. The Web site disclosure in condition (5) above must be promptly updated if a material change occurs with respect to any information contained in the disclosure.

This exemptive relief expires when the pilot terminates, and is subject to modification or revocation at any time the Commission determines that such action is necessary or appropriate in furtherance of the purposes of the Exchange Act. This exemptive relief is limited solely to the payment of the Optional Incentive Fee as set forth in New Rule 8.800 for a security that is an ETP participating in the Program,[30] and does not extend to any other activities, any other security of the trust related to the participating ETP, or any other issuers.[31] In addition, persons relying on this exemption are directed to the anti-fraud and anti-manipulation provisions of the Exchange Act, particularly Sections 9(a) and 10(b), and Rule 10b–5 thereunder. Responsibility for compliance with these and any other applicable provisions of the federal securities laws must rest with the persons relying on this exemption. This order does not represent Commission views with respect to any other question that the proposed activities may raise, including, but not limited to the adequacy of the disclosure required by federal securities laws and rules, and the applicability of other federal or state laws and rules to, the proposed activities.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–13887 Filed 6–11–13; 8:45 am]

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[30] All ETPs that are allowed to participate in the Program have a pool of underlying assets. *See* New Rule 8.800(a)(2). Should the program be modified to include other ETPs, such as exchange-traded notes, that do not have a pool of underlying assets, the Commission would consider this a material change and outside the scope of this exemptive relief.

[31] Other activities, such as ETP redemptions, are not covered by this exemptive relief.

[32] 17 CFR 200.30–3(a)(6).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69708; File No. SR–FICC–2013–01]

Self-Regulatory Organizations; The Fixed Income Clearing Corporation; Order Granting Approval of a Proposed Rule Change To Amend the Mortgage-Backed Securities Division Rule To Reflect Recommendations of the Treasury Market Practice Group

June 6, 2013.

I. Introduction

On April 15, 2013, the Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') proposed rule change SR–FICC–2013–01 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder.[2] The proposed rule change was published for comment in the **Federal Register** on April 29, 2013.[3] The Commission received no comment letters. This order approves the proposed rule change.

II. Description

To address the persistent settlement fails in agency debt and mortgage-backed securities (''MBS'') transactions and to encourage market participants to resolve such fails promptly, the Treasury Market Practices Group (''TMPG'') recommended in February 2012 that the MBS market impose a fails charge.[4] FICC's Mortgage-Backed Securities Division (''MBSD'') amended Rule 12 (Fails Charges) of MBSD's

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 69424 (April 22, 2013), 78 FR 25115 (April 29, 2013).

[4] The TMPG is a group of market participants active in the treasury securities market sponsored by the Federal Reserve Bank of New York.

Clearing Rules in March 2012 to reflect TMPG's recommendations.[5] The fails charge for MBS transactions applies to certain trades settled in the MBSD central counterparty (''CCP'') (*i.e.*, settlement of pools versus FICC involving failing agency MBS issued or guaranteed by Fannie Mae, Freddie Mac, and Ginnie Mae.) Consistent with the TMPG's initial recommendation, MBSD's Rule 12 did not impose a fails charge if delivery occurred on either of the two business days following the contractual settlement date. The two business days are sometimes referred to as the ''resolution period.''

However, on March 1, 2013, the TMPG issued a new recommendation to remove the two-day resolution period from the current practice.[6] The TMPG has advised that the revised recommendation should apply to transactions in agency MBS transactions entered into on or after July 1, 2013, as well as to transactions that were entered into prior to but remain unsettled as of July 1, 2013. This rule change amends the existing fails charge rule to reflect TMPG's most recent recommendation by removing the two-day resolution period provision from the rule. Consequently, an agency MBS settlement fail will be subject to a fails charge for each calendar day that the fail is outstanding, even if the delivery occurs on either of the first two business days following the contractual settlement date. FICC is making the rule change effective as of July 1, 2013, in accordance with the TPMG's recommendation. All other provisions of the agency MBS fails charge rule, including the fails charge rate and trading practices, remain unchanged.

III. Discussion

Section 19(b)(2)(C) of the Act[7] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization. Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.[8] The Commission finds that FICC's rule change should facilitate the prompt and accurate clearance and settlement of securities transactions because the rule change will discourage persistent settlement fails in agency debt and MBS transactions and encourage market participants to resolve such fails promptly.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, particularly with the requirements of Section 17A of the Act, and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[9] that the proposed rule change (File No. SR–FICC–2013–01) be and hereby is approved.[10]

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[11]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–13888 Filed 6–11–13; 8:45 am]

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[5] *See* Securities Exchange Act Release No. 66550 (March 9, 2012), 77 FR 15155 (March 14, 2012) (File No. SR–FICC–2008–01).

[6] Press Release, Federal Reserve Bank of New York, TMPG Revises Agency MBS Fails Charge Trading Practice (March 1, 2013) (available at *www.newyorkfed.org/tmpg/03_01_2013_Fails_charges_press_release.pdf).*

[7] 15 U.S.C. 78s(b)(2)(C).

[8] 15 U.S.C. 78q–1(b)(3)(F).

[9] 15 U.S.C. 78s(b)(2).

[10] In approving this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69709; File No. SR–FICC–2013–03]

Self-Regulatory Organizations; The Fixed Income Clearing Corporation; Order Granting Approval of a Proposed Rule Change To Amend Mortgage-Backed Securities Division Rules Relating To Allocation of an Indemnity Claim Made in Connection With the Use of the Federal Reserve's National Settlement Service

June 6, 2013.

I. Introduction

On April 15, 2013, the Fixed Income Clearing Corporation (''FICC'') filed with the Securities and Exchange Commission (''Commission'') proposed rule change SR–FICC–2013–03 pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder.[2] The proposed rule change was published for comment in the **Federal Register** on April 29, 2013.[3] The Commission received no comment letters. This order approves the proposed rule change.

II. Description

FICC's Government Securities Division (''GSD'') and Mortgage-Backed Securities Division (''MBSD'') each use the Board of Governors of the Federal Reserve's (''FRB'') National Settlement Service (''NSS'') for Funds-Only Settlement[4] and Cash Settlement[5] purposes, respectively. GSD's Rule 13 and MBSD's Rule 11 address the situation where the FRB makes an indemnity claim in connection with the use of the NSS service by FICC. Pursuant to the GSD and MBSD rules, if FICC receives an FRB indemnity claim, FICC will apportion the entire liability to the GSD netting members or MBSD clearing members, as applicable, for whom the settling bank was acting at the time.[6] If such amounts are not sufficient to fully satisfy the FRB indemnity claim, each of the GSD and MBSD rules currently provide different directives as to how FICC should handle the remaining loss. The GSD rules state that FICC will treat the remaining loss as an ''Other Loss,'' as defined in GSD Rule 4, and allocate accordingly.[7] In contrast, MBSD Rule 11, Section 5(o), states that FICC will allocate the remaining loss among all MBSD clearing members in proportion to their relative use of the MBSD services (based on fees).

The purpose of the rule change is to correct MBSD's Rule 11 in order to accurately reflect the correct manner in which FICC should allocate an indemnity claim made in connection with the use of the FRB's NSS. The MBSD provision in Rule 11 was drafted prior to the MBSD becoming a central counterparty and adopting a loss mutualization process similar to the GSD process. When FICC filed its rule change to provide guaranteed settlement

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Securities Exchange Act Release No. 69434 (April 23, 2013), 78 FR 25121 (April 29, 2013).

[4] ''Fund-Only Settlement Amount'' is defined under Rule 1 of GSD's Rulebook as the net dollar amount of a netting member's obligation, calculated pursuant to GSD's Rule 13, either to make a funds-only payment to GSD or to receive a funds-only payment from GSD. *See* GSD Rule 13 for the rules related to funds-only settlement.

[5] ''Cash Settlement'' is defined under Rule 1 of MBSD's Clearing Rules as the payment each business day by MBSD to a member or by a member to MBSD. See MBSD Rule 11 for the rules related to cash settlement.

[6] See GSD's Rule 13 Section 5(o) and MBSD Rule 11, Section 5(o).

[7] Rule 4(f) of GSD's Rulebook.

and central counterparty services,[8] which among other things established the loss mutualization process, the MBSD NSS indemnity provision requiring the current loss allocation process was inadvertently overlooked and therefore not updated during FICC's efforts to harmonize the GSD and MBSD rules. Accordingly, the rule change corrects this oversight by revising MBSD Rule 11, Section 5(o), to reflect that all remaining losses from a FRB indemnity claim should be treated as an ''Other Loss'' as defined in MBSD Rule 4 and allocated accordingly.

III. Discussion

Section 19(b)(2)(C) of the Act[9] directs the Commission to approve a proposed rule change of a self-regulatory organization if it finds that such proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to such organization. Section 17A(b)(3)(F) of the Act requires, among other things, that the rules of a clearing agency be designed to promote the prompt and accurate clearance and settlement of securities transactions and to remove impediments to and perfect the mechanism of a national system for the prompt and accurate clearance and settlement of securities transactions.[10] The Commission finds that FICC's rule change should facilitate the prompt and accurate clearance and settlement of securities transactions by correcting MBSD's rules to accurately reflect the loss allocation procedures in connection with NSS and to ensure that there is consistent treatment of such losses between the MBSD and GSD rules.

IV. Conclusion

On the basis of the foregoing, the Commission finds that the proposed rule change is consistent with the requirements of the Act, particularly with the requirements of Section 17A of the Act, and the rules and regulations thereunder.

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[11] that the proposed rule change (File No. SR–FICC–2013–03) be and hereby is approved.[12]

For the Commission by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–13889 Filed 6–11–13; 8:45 am]

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[8] Exchange Act Release No. 66550 (March 9, 2012), 77 FR 15155 (March 14, 2012) [File No. SR–FICC–2008–01] (order approving amended proposed rule change to allow MBSD to provide guaranteed settlement and central counterparty services).

[9] 15 U.S.C. 78s(b)(2)(C).

[10] 15 U.S.C. 78q–1(b)(3)(F).

[11] 15 U.S.C. 78s(b)(2).

[12] In approving this proposal, the Commission has considered its impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69703; File No. SR–ICEEU–2013–09]

Self-Regulatory Organizations; ICE Clear Europe Limited; Notice of Filing of Amendment No. 2 to Proposed Rule Change To Clear Contracts Traded on the LIFFE Administration and Management Market

June 5, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder[2] notice is hereby given that on June 4, 2013, ICE Clear Europe Limited (''ICE Clear Europe'') filed with the Securities and Exchange Commission (''Commission'') Amendment No. 2 to its previously submitted proposed rule changes to implement a clearing relationship in which ICE Clear Europe will clear contracts traded on the LIFFE Administration and Management (''LIFFE A&M'') market (the ''LIFFE Clearing Proposed Amendments'').[3] Amendment No. 2 is intended to elaborate on certain aspects of the proposed clearing activities as they relate to LIFFE securities products and make a partial amendment to certain rules and procedures that would clarify the considerations under which certain margin and risk management requirements would be established and modified from time to time, as described in Items I, II, and III below, which Items have been prepared primarily by ICE Clear Europe. Except as described in this Amendment No. 2, the LIFFE Clearing Proposed Amendments, as described in the LIFFE Clearing Rule Notice, are unchanged. The Commission is publishing this notice to solicit comments on Amendment No. 2 to the proposed change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

As described in the LIFFE Clearing Rule Notice, ICE Clear Europe has agreed to act as the clearing organization for futures and option contracts traded on LIFFE Administration and Management, a recognized investment exchange under the UK Financial Services and Markets Act of 2000. Capitalized terms used but not defined herein have the meanings specified in the LIFFE Clearing Rule Notice. In this Amendment No. 2, ICE Clear Europe submits revisions to Rule 502 and Sections 13.6 and 13.7 of the Finance Procedures that are intended to clarify the considerations under which ICE Clear Europe would establish and modify certain margin requirements that may be applicable to cleared LIFFE Contracts and energy contracts, including the assets eligible as Margin and Permitted Cover and related haircuts.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICE Clear Europe included statements concerning the purpose of and basis for the additional rule change in Amendment No. 2. The text of these statements may be examined at the places specified in Item IV below. ICE Clear Europe has prepared summaries, set forth in sections A, B, and C below, of the significant aspects of these statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(a) Purpose

ICE Clear Europe submits revisions to its margin requirements under Rule 502 and Sections 13.6 and 13.7 of the Finance Procedures. As discussed in the LIFFE Clearing Rule Notice, Margin requirements for LIFFE Contracts will be calculated using the SPAN®1 v4 algorithm,[4] with modifications for

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] On May 13, 2013, ICE Clear Europe initially filed the LIFFE Clearing Proposed Amendments. On May 22, 2013, ICE Clear Europe submitted Amendment No. 1 to the proposed rule change to, among other things, clarify the scope of products proposed to be cleared, add new Rule 207(f) prohibiting FCM/BD Clearing Members and other Clearing Members organized in the U.S. from clearing LIFFE Contracts that are futures or options on underlying U.S. securities, add additional clarification surrounding the operation of the combined F&O Guaranty Fund and the margining of LIFFE Contracts, and supplement the statutory basis for the proposed rule change. *See* Securities Exchange Act Release No. 69628 (May 23, 2013), 78 FR 32287 (May 29, 2013) (SR–ICEEU–2013–09) (''LIFFE Clearing Rule Notice'').

[4] SPAN is a registered trademark of Chicago Mercantile Exchange Inc. and used by ICE Clear

Continued

concentration charges and a trinomial model used with respect to certain LIFFE option transactions. ICE Clear Europe will determine the margin parameters used in the SPAN algorithm for LIFFE Contracts cleared by ICE Clear Europe, and make appropriate modifications to those parameters from time to time, within the framework of the margin requirement policy approved by the ICE Clear Europe F&O Risk Committee. The margin parameters applicable from time to time will be issued and amended by ICE Clear Europe via a circular posted on its Web site.

Rule 502(d) addresses a number of margin requirements, including the assets eligible to be provided as Margin or Permitted Cover, and Rule 502(e) addresses haircuts that the clearing house may apply to such assets. Under the existing Rules, changes to such requirements may be determined by the clearing house from time to time and notified by Circular (which will also be posted on the clearing house's Web site). ICE Clear Europe proposes to add a new Rule 502(k) to provide that for F&O Contracts, changes to the matters set forth in Rules 502(d) and (e), including assets eligible as Margin or Permitted Cover and the haircuts established with respect to such assets, will be based on an analysis of appropriate factors as determined by the clearing house. These factors will include, without limitation, historical and implied price volatility of those assets, current and anticipated conditions in the market for those assets, spreads and correlations between assets, liquidity in the trading market for those assets, composition of the relevant market, default risk (including sovereign risk) with respect to those assets, relevant foreign exchange market conditions and other relevant information as determined by ICE Clear Europe. Consistent with its existing policies and procedures, ICE Clear Europe regularly reviews its current eligible Margin and Permitted Cover assets and related haircuts and makes any necessary adjustments.

Proposed new Rule 502(k) reads as follows:

(k) With respect to F&O Contracts, changes to the matters described in Rules 502(d) and (e) above, including assets eligible as Margin or Permitted Cover and the haircuts established with respect thereto, will be based on an analysis of appropriate factors as determined by the Clearing House, including historical and implied price volatility of such assets, current and anticipated conditions in the market for those assets, spreads and correlations between relevant assets, liquidity in the trading market for those assets, composition of the relevant market, default risk (including sovereign risk) with respect to those assets, relevant foreign exchange market conditions and other relevant information.

Similarly existing Section 13.6 of the Finance Procedures addresses the determination and change of original margin rates from time to time. As set forth in existing Section 13.6, ICE Clear Europe regularly reviews its margin rates in light of market conditions and makes appropriate modifications. ICE Clear Europe proposes to amend Section 13.6 to provide that changes to original margin rates for F&O Contracts will be based on an analysis of appropriate factors as determined by the clearing house. These include market prices, historical and implied volatilities of relevant contracts, spreads and correlations between related commodities, other current and anticipated conditions (including liquidity) in the market for the contracts and other relevant information as determined by ICE Clear Europe. ICE Clear Europe believes that Section 13.6 provides it the flexibility to adjust the calculation of margin rates in order to react to changes in market conditions, particularly changes in volatility. These changes may occur suddenly, and failure to update margin rates to take into account such changes may lead to insufficient margin being collected by the clearing house. The proposed revisions to Section 13.7 of the Finance Procedures are substantially the same as the amendments to Rule 502(k), and are being made for the reasons discussed above in connection with that rule change.

Proposed amended Sections 13.6 and 13.7 of the Finance Procedures read as follows (new text italicized):

13.6 Margin Parameters The Clearing House monitors market volatilities on a daily basis. The Clearing House will review Original Margin rates on a periodic and ad hoc basis. Changes to Original Margin rates will be notified to Clearing Members by Circular. *With respect to F&O Contracts,* ad hoc rate changes will become effective on the next Business Day. Routine rate changes will be implemented on the date given in the Circular announcing such changes, normally five Business Days after the date of the Circular. *With respect to F&O Contracts, changes to Original Margin rates will be based on an analysis of appropriate factors as determined by the Clearing House, including market prices, historical and implied volatilities of relevant contracts, spreads and correlations between related commodities, other current and anticipated conditions (including liquidity) in the market for the contracts and other relevant information.*

13.7 Haircuts The Clearing House will review haircuts applicable for Permitted Cover on a periodic and ad hoc basis. Changes to haircuts will be notified to Clearing Members by Circular. *With respect to Permitted Cover for F&O Contracts,* ad hoc rate changes will become effective on the next Business Day. Routine rate changes will be implemented on the date given in the Circular announcing such changes, normally five Business Days after the date of the Circular. *With respect to Permitted Cover for F&O Contracts, changes to haircuts will be based on an analysis of appropriate factors as determined by the Clearing House, including historical and implied price volatility of such assets, current and anticipated conditions in the market for those assets, spreads and correlations between relevant assets, liquidity in the trading market for those assets, composition of the relevant market, default risk (including sovereign risk) with respect to those assets, relevant foreign exchange market conditions and other relevant information.*

ICE Clear Europe believes that the proposed revisions to Rule 502 and Sections 13.6 and 13.7 of the Finance Procedures will provide clearing members with additional predictability as to potential changes to margin requirements, and the reasons for such changes, without adversely affecting the clearing house's ability to adjust margin requirements as warranted by its risk management policies and market conditions. In addition, this additional guidance should permit clearing members to better anticipate potential changes in margin requirements and manage their own liquidity requirements, which may reduce the likelihood that a clearing member will be unable to satisfy its margin requirements and thereby improve the financial stability of the clearing house.

(b) Statutory Basis

As discussed in the LIFFE Clearing Rule Notice, ICE Clear Europe proposes to clear, among other LIFFE contracts, the LIFFE securities products. Currently, the LIFFE securities products are cleared by LIFFE A&M, with certain clearing functions performed by LCH Clearnet Limited, as described in the no-action relief previously provided to LIFFE A&M and its predecessor entities by Commission staff.[5] ICE Clear Europe proposes to provide substantially the same clearing functions for the LIFFE securities products, pursuant to the LIFFE Clearing Proposed Amendments,

Europe under license. SPAN is a risk evaluation and margin framework algorithm.

[5] *See, e.g.,* SEC No-Action Letter to LIFFE A&M, dated July 29, 2009; SEC No-Action Letter to LIFFE A&M, dated March 6, 1996; SEC No-Action Letter to LIFFE A&M, dated May 1, 1992.

as are currently being provided by LIFFE A&M and LCH Clearnet.

ICE Clear Europe is currently registered with the Commission as a securities clearing agency for purposes of clearing security-based swaps, pursuant to Section 17A(l) of the Act.[6] With respect to the clearing of other securities products, such as the options on securities and security indices that constitute LIFFE securities products, the Commission has historically taken the position that a foreign clearing agency would be required to register as a securities clearing agency (or obtain an exemption from registration) only if it provides clearing services for U.S. securities directly to U.S. persons.[7] Conversely, the Commission has recognized that a foreign clearing agency is not required to register, or obtain an exemption from registration, with respect to clearing services involving non-U.S. securities, even if such services may be provided directly to U.S. persons.[8]

Consistent with these Commission positions, ICE Clear Europe believes that its proposed clearing of the LIFFE securities products does not require further registration of ICE Clear Europe or an exemption from the registration requirement. With respect to those LIFFE securities products that constitute foreign securities (i.e., futures and options on underlying non-U.S. securities), ICE Clear Europe (as a foreign clearing organization) may, consistent with the approach taken under Euroclear Order, provide clearing services, including to U.S. clearing members, without registration. With respect to those LIFFE securities products that may constitute U.S. securities (i.e., futures and options on underlying U.S. securities), ICE Clear Europe will not provide clearing services to U.S. clearing members, as provided in proposed new Rule 207(f) and as described in the LIFFE Clearing Rule Notice. As a result, these clearing activities do not implicate the registration requirement under Section 17A(b) of the Act.[9]

In ICE Clear Europe's view, the fact that it is registered as a securities clearing agency for purposes of clearing security-based swaps does not change this analysis. ICE Clear Europe's security-based swap clearing activities are for relevant purposes separate from the proposed LIFFE securities product clearing activities, and in particular are supported by a separate guaranty fund. ICE Clear Europe believes that they can be treated separately as a regulatory matter as well. The Commission has recognized in the Euroclear Order, for example, that a foreign clearing organization may have activities for which registration (or exemption) is needed and activities for which neither registration nor exemption is required. Similarly, ICE Clear Europe's registration for security-based swap clearing should not preclude it from engaging in other clearing activities that would otherwise be permissible without registration under the Exchange Act. (ICE Clear Europe notes that in any event, because of its status as a registered clearing agency, it will in practice be subject to additional requirements under the Act in respect of the LIFFE securities products, notably the rule approval requirements under Section 19(b) of the Act.)

As described in the LIFFE Clearing Rule Notice, ICE Clear Europe's clearing operations with respect to the LIFFE securities products, and particularly those relating to U.S. securities, will be conducted outside the United States (with the exception of certain information technology services obtained from U.S. affiliates). Although ICE Clear Europe obtains certain services from some of its U.S. affiliates in connection with its security-based swap clearing activities, those services are not relevant to the clearing of the LIFFE securities products. Accordingly, ICE Clear Europe does not believe such arrangements would affect the analysis discussed above.

As noted above, ICE Clear Europe's proposed new Rule 207(f) will prohibit U.S. clearing members from clearing LIFFE securities products involving underlying U.S. securities (other than broad-based security index futures contracts). In furtherance of this restriction, ICE Clear Europe, together with LIFFE, will implement operational controls to restrict the activities of U.S. clearing members. Specifically, the clearing system to be used for the LIFFE securities products will have market access controls that prevent U.S. clearing members from creating or holding cleared positions in LIFFE securities products involving underlying U.S. securities. This is intended to prevent U.S. clearing members from engaging in any clearing-related activity (including give-ups or take-ups) in respect of those products. When a new U.S. clearing member is approved for clearing, LIFFE and ICE Clear Europe will be jointly responsible to ensure that these access limitations are properly in place.

With respect to the proposed changes to Rule 502 and Sections 13.6 and 13.7 of the Finance Procedures in this Amendment No. 2, ICE Clear Europe believes that such amendments are consistent with the requirements of Section 17A of the Act[10] and the regulations thereunder applicable to it, including the standards under Rule 17Ad–22.[11] The amendments will promote the prompt and accurate clearance of and settlement of securities transactions, the safeguarding of securities and funds in the custody or control of ICE Clear Europe, and the protection of investors and the public interest, within the meaning of Section 17A(b)(3)(F) of the Act.[12] Specifically, ICE Clear Europe believes that the amendments will facilitate the safeguarding of securities and funds in the custody or control of ICE Clear Europe, including the F&O Guaranty Fund that applies to LIFFE contracts and energy contracts, in a manner that is consistent with the financial resources and risk management requirements of Rule 17Ad–22[13] and the rule change approval requirements of Section 19(b)(1) of the Act[14] and Commission Rule 19b–4.[15] In addition, ICE Clear Europe believes that its other risk management practices applicable to clearing in the F&O Contracts can be conducted consistent with its rule change approval requirements of Section 19(b)(1) of the Act[16] and Commission Rule 19b–4.[17]

B. Self-Regulatory Organization's Statement on Burden on Competition

ICE Clear Europe does not believe the proposed rule changes in this Amendment No. 2 would have any impact, or impose any burden, on competition. ICE Clear Europe does not anticipate that the rule changes will adversely affect the trading market for the LIFFE contracts on LIFFE A&M. Moreover, ICE Clear Europe does not believe that the proposed amendments will impose any burden on competition among clearing members.

[6] 15 U.S.C. 78q–1(l).

[7] *See, e.g.,* Cross-Border Security-Based Swap Activities, Securities Exchange Act Release No. 69490 (May 1, 2013), 78 FR 30967, 31039 n. 682 (May 23, 2013).

[8] *See, e.g.,* Morgan Guaranty Trust Company of New York, Brussels Office, as Operator of the Euroclear System, Securities Exchange Act Release No. 38589 (May 9, 1997), 62 FR 26833, 26835 n. 16 (May 15, 1997) (''Euroclear Order'').

[9] 15 U.S.C. 78q–1(b).

[10] 15 U.S.C. 78q–1.

[11] 17 CFR 240.17Ad–22.

[12] 15 U.S.C. 78q–1(b)(3)(F).

[13] 17 CFR 240.17Ad–22.

[14] 15 U.S.C. 78s(b)(1).

[15] 17 CFR 240.19b–4.

[16] 15 U.S.C. 78s(b)(1).

[17] 17 CFR 240.19b–4.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to Amendment No. 2 have not been solicited or received. ICE Clear Europe will notify the Commission of any written comments received by ICE Clear Europe.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of the LIFFE Clearing Rule Notice [18] in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove the proposed rule change or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*) or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–ICEEU–2013–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–ICEEU–2013–09. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filings also will be available for inspection and copying at the principal office of ICE Clear Europe and on ICE Clear Europe's Web site at *https://www.theice.com/publicdocs/regulatory_filings/ICEU_SEC_060413.pdf*.

All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ICEEU–2013–09 and should be submitted on or before June 27, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–13859 Filed 6–11–13; 8:45 am]

BILLING CODE 8011–01–P

[18] *See supra* note 3.

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69711; File No. SR–BOX–2013–29]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend BOX Rule 8050 to Lower the Minimum Quoting Requirement for Market Makers Quoting in Jumbo SPY Options

June 6, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on May 31, 2013, BOX Options Exchange LLC (''BOX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 8050 to lower the minimum quoting requirement for Market Makers quoting in Jumbo SPY Options. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com.*

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On May 10, 2013 the Exchange began listing and trading option contracts overlying 1,000 SPDR® S&P 500® exchange-traded fund shares (''SPY''),[3] or (''Jumbo SPY Options'').[4] Whereas standard options contracts represent a deliverable of 100 shares of an underlying security, this product represents 1,000 SPY shares. Except for the difference in the number of deliverable shares, Jumbo SPY Options have the same terms and contract characteristics as regular-sized options contracts (''standard options''), including exercise style. Accordingly, the Commission noted in the approval order that the Exchange's rules that apply to the trading of standard options would apply to Jumbo SPY Options as

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''SPDR®,'' ''Standard & Poor's®,'' ''S&P®,'' ''S&P 500®,'' and ''Standard & Poor's 500'' are registered trademarks of Standard & Poor's Financial Services LLC. The SPY ETF represents ownership in the SPDR S&P 500 Trust, a unit investment trust that generally corresponds to the price and yield performance of the SPDR S&P 500 Index.

[4] *See* Securities Exchange Act Release No. 34–69511 (May 3, 2013), 78 FR 27271 (May 9, 2013) (Order Approving SR–BOX–2013–06).

well.[5] The Exchange proposes to amend BOX Rule 8050 to lower the minimum quoting requirement for Market Makers quoting in Jumbo SPY Options.

Currently, the Exchange requires that a Market Maker's bid and offer for a series of options contracts shall be accompanied by the number of contracts at that price the Market Maker is willing to buy from or sell to Customers. Every Market Maker bid or offer must have an initial size of at least ten (10) contracts.[6] The Exchange proposes to lower the Market Maker bid or offer initial size requirement for Jumbo SPY options to 1/10th of the current requirement. Specifically, the Exchange proposes to make the required minimum number of contracts for a Market Maker's bid or offer in Jumbo SPY Options one (1) contract.

The Exchange believes it is appropriate to adjust the Market Maker quoting requirement for Jumbo SPY Options so it is scaled based upon the total number of shares of the underlying security instead of the total number of options contracts. Under the proposed rule change a Market Maker would be required to quote at least ten (10) contracts for standard options that represent a total of 1,000 shares of the underlying security. For Jumbo SPY Options the Market Maker would only be required to quote at least one (1) contract, but this would still represent a total of 1,000 shares of the underlying security. The Exchange believes that modifying the quotation requirement for Jumbo SPY Options will encourage Market Maker quoting in this new product and lead to increased liquidity.

The Exchange notes that a minimum quoting requirement of one (1) contract is not novel and certain exchanges have a minimum quoting requirement of one (1) contract for all classes.[7] Further, the Exchange believes that having different quotation requirements for Jumbo SPY Options than those required for standard options on SPY would not lead to investor confusion and will instead increase liquidity in this new product, therefore enabling market participants to trade Jumbo SPY Options with greater precision.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[8] in general, and Section 6(b)(5) of the Act,[9] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general to protect investors and the public interest. The proposed rule change will assure that standard options and Jumbo SPY Options will have an equivalent Market Maker quoting requirement in terms of shares on the underlying security. The Exchange believes that investors and other market participants will benefit from this proposed rule change because it establishes a lower quoting requirement for Jumbo SPY Options, which will increase the overall liquidity in this new product.

Finally, the Exchange believes that the proposed rule change is not designed to permit unfair discrimination among market participants as all Market Makers may quote Jumbo SPY Options once they are appointed to this options class.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that investors will benefit from the increased liquidity of Jumbo SPY Options. Quoting in Jumbo SPY Options is entirely voluntary and Market Makers can determine if they would like to trade in this new product. The Exchange believes this proposed rule change is necessary to establish equivalent Market Maker quoting requirements for Jumbo SPY Options, a new options product.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change: (1) Does not significantly affect the protection of investors or the public interest; (2) does not impose any significant burden on competition; and (3) by its terms does not become operative for 30 days after the date of this filing, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11]

A proposed rule change filed under Rule 19b–4(f)(6) normally does not become operative for 30 days after the date of filing. However, Rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requests that the Commission waive the 30-day operative delay so that the proposed rule change may become immediately operative. The Commission believes that waiving the 30-day operative delay is consistent with the protection of investors and the public interest.[12] The Exchange began trading Jumbo SPY Options on May 10, 2013, and waiver of the operative delay will allow the Exchange to implement its proposal without delay. For these reasons, the Commission designates the proposed rule change as operative upon filing.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or

[5] *Id.*

[6] BOX Rule 8050(b).

[7] *See* NASDAQ OMX BX Rule Chapter VII, Sec. 6 (Market Maker Quotations).

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires a self-regulatory organization to provide the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has fulfilled this requirement.

[12] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

• Send an email to *rule-comments@sec.gov.* Please include File Number SR–BOX–2013–29 on the subject line.

Paper Comments

• Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BOX–2013–29. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BOX–2013–29 and should be submitted on or before July 3, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–13882 Filed 6–11–13; 8:45 am]

BILLING CODE 8011–01–P

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69706; File No. SR–NYSEArca–2013–34]

Self-Regulatory Organizations; NYSE Arca, Inc.; Order Granting Approval of a Proposed Rule Change, as Modified by Amendment Nos. 1 and 2 Thereto, To Implement a One-Year Pilot Program for Issuers of Certain Exchange-Traded Products Listed on the Exchange

June 6, 2013.

On March 21, 2013, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'')[1] and Rule 19b–4 thereunder,[2] a proposed rule change to implement the NYSE Arca ETP Incentive Program (''Incentive Program''), a one-year pilot program for issuers of certain exchange-traded products (''ETPs'') listed on the Exchange. On April 5, 2013, the Exchange submitted Amendment No. 1 to the proposed rule change, which replaced and superseded the proposed rule change in its entirety.[3] The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on April 11, 2013.[4] The Commission received two comment letters on the proposal.[5] On May 29, 2013, the Exchange submitted Amendment No. 2 to the proposed rule change.[6] This order grants approval of the proposed rule change, as modified by Amendment Nos. 1 and 2 thereto.[7]

I. Description of the Proposal

As set forth in more detail in the Notice,[8] the Exchange is proposing to adopt new NYSE Arca Equities Rule 8.800 and to amend its fee schedules to set forth the requirements for the Incentive Program, which will be a one-year pilot program for issuers of certain ETPs listed on the Exchange.[9] The Exchange states that the Incentive Program is designed to enhance the market quality for ETPs by incentivizing Market Makers[10] to take Lead Market Maker (''LMM'') assignments in certain lower volume ETPs by offering an alternative fee structure for such LMMs that would be funded from the Exchange's general revenues.[11] The Exchange states that participation in the Incentive Program would be entirely voluntary on the part of both LMMs and issuers, and that the costs of the Incentive Program would be offset by charging participating issuers non-refundable ''Optional Incentive Fees,'' which would be credited to the Exchange's general revenues.[12]

A. Eligible Products, Issuer Application, and LMM Assignment

An ETP will be eligible to participate in the Incentive Program if (i) it is listed

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] SR–NYSEArca–2013–34 replaced and superseded SR–NYSEArca–2012–37, which was withdrawn by the Exchange. *See* Securities Exchange Act Release Nos. 66966 (May 11, 2012), 77 FR 29419 (May 17, 2012) and 68616 (Jan. 10, 2013), 78 FR 3482 (Jan. 16, 2013) (SR–NYSEArca–2012–37).

[4] *See* Securities Exchange Act Release No. 69335 (Apr. 5, 2013), 78 FR 21681 (''Notice'').

[5] *See* Letter from John T. Hyland, Chief Investment Officer, United States Commodity Funds LLC, dated Apr. 10, 2013 (''USCF Letter''), and Letter from Stanislav Dolgopolov, Assistant Adjunct Professor, UCLA School of Law, dated Apr. 26, 2013 (''Dolgopolov Letter'').

[6] In Amendment No. 2, the Exchange proposed to: (i) amend the rule text to provide that an LMM in the Incentive Program will remain obligated to satisfy the general requirements of NYSE Arca Equities Rule 7.23, rather than the general requirements of NYSE Arca Rule 7.23; (ii) amend the rule text to provide that the Exchange will disclose on its Web site the date it receives written notice of an issuer's intent to withdraw its ETP from the Incentive Program, or an LMM's (as defined herein) intent to withdraw from its ETP assignment(s) in the Incentive Program, and, in each case, the intended withdrawal date, if provided; and (iii) clarify that the Exchange's monthly public report to the Commission relating to the Incentive Program will (a) compare, to the extent practicable, ETPs before and after they are in the Incentive Program, and will further provide data and analysis about the market quality of ETPs that exceed the one million CADV (as defined herein) threshold and ''graduate,'' or are otherwise withdrawn or terminated from, the Incentive Program, and (b) include market quality data for comparable ETPs that are listed on the Exchange but not participating in the Incentive Program. Amendment No. 2 provides clarification to the proposed rule change, and because it does not materially affect the substance of the proposed rule change, Amendment No. 2 does not require notice and comment.

[7] Today the Commission also is granting exemptive relief from Rule 102 under Regulation M concerning the Incentive Program. *See* Securities Exchange Act Release No. 69707 (June 6, 2013) (Order Granting a Limited Exemption from Rule 102 of Regulation M Concerning the NYSE Arca, Inc.'s Exchange-Traded Product Incentive Program Pilot Pursuant to Regulation M Rule 102(e)).

[8] *See* Notice, *supra* note 4.

[9] The Exchange currently has two Schedules of Fees and Charges for Exchange Services; one that is for listings (''Listing Fee Schedule'') and another that is for trade-related charges (''Trading Fee Schedule''). To differentiate them, the Exchange also proposes to change the name of the Listing Fee Schedule to ''Schedule of Fees and Charges for Exchange Listing Services.''

[10] A Market Maker is an Equity Trading Permit Holder (''ETP Holder'') that acts as a Market Maker pursuant to NYSE Arca Equities Rule 7. *See* NYSE Arca Equities Rule 1.1(v). An ETP Holder is a sole proprietorship, partnership, corporation, limited liability company, or other organization in good standing that has been issued an Equity Trading Permit. *See* NYSE Arca Equities Rule 1.1(n).

[11] *See* Notice, *supra* note 4, at 21682.

[12] *Id.*

on the Exchange as of the commencement of the pilot period or becomes listed during the pilot period; (ii) the listing is under NYSE Arca Equities Rules 5.2(j)(3) (Investment Company Units), 5.2(j)(5) (Equity Gold Shares), 8.100 (Portfolio Depositary Receipts), 8.200 (Trust Issued Receipts), 8.201 (Commodity-Based Trust Shares), 8.202 (Currency Trust Shares), 8.203 (Commodity Index Trust Shares), 8.204 (Commodity Futures Trust Shares), 8.300 (Partnership Units), 8.600 (Managed Fund Shares), or 8.700 (Managed Trust Securities); (iii) with respect to an ETP that listed on the Exchange before the commencement of the Incentive Program, the ETP has a consolidated average daily volume (''CADV'') of one million shares or less for at least the preceding three months and the issuer of such ETP has not suspended the issuance or redemption of new shares; [13] and (iv) it is compliant with continuing listing standards, if the ETP was added to the Incentive Program after listing on the Exchange.[14]

An issuer that wishes to have an ETP participate in the Incentive Program and pay the Exchange an Optional Incentive Fee will be required to submit a written application in a form prescribed by the Exchange for each ETP.[15] An issuer may apply to have its ETP participate at the time of listing or thereafter at the beginning of each quarter during the pilot period.[16] An issuer may not have more than five ETPs that were listed on the Exchange prior to the pilot period participate in the Incentive Program.[17] However, there will be no limitation on the number of ETPs per issuer listed during the pilot period that can participate in the program.[18] In order for its ETP to be eligible to participate in the Incentive Program, an issuer must be current in all payments due to the Exchange.[19]

Proposed NYSE Arca Equities Rule 8.800(b)(3) provides that the Exchange will communicate the ETP(s) proposed for inclusion in the Incentive Program on a written solicitation that will be sent to all qualified LMMs [20] along with the Optional Incentive Fee the issuer will pay the Exchange for each ETP. The issuer will determine the amount of the Optional Incentive Fee for each ETP within a permitted range that will be set forth in the Exchange's Listing Fee Schedule.[21] Proposed NYSE Arca Equities Rule 8.800(b)(4) provides that after the Exchange provides the written solicitation to LMMs, no individual associated with an LMM may contact such issuer or the Exchange staff about that ETP until the assignment of the LMM is made, except as otherwise permitted in the proposed rules. If more than one qualified LMM proposes to serve as such for a particular ETP, Exchange staff will select the LMM pursuant to the provisions set forth in the proposed rules.[22] The issuer of the ETP may choose to submit a letter to the Exchange staff indicating its preference and supporting justification for a particular LMM, and the Exchange staff may consider such letter in performing its duty to select an LMM, but such letter will not be determinative of the particular LMM selected by the Exchange.[23] Within two business days after the final LMM interview, the Exchange staff, in its sole discretion, will select an LMM and notify the LMM and the issuer.[24]

B. Disclosure Relating to the Incentive Program

Pursuant to proposed NYSE Arca Equities Rule 8.800(b)(6), the Exchange will provide notification on a dedicated page on its Web site regarding: (i) The ETPs participating in the Incentive Program; (ii) the date a particular ETP begins participating and ceases participating in the Incentive Program; (iii) the LMM assigned to each ETP participating in the Incentive Program; (iv) the date the Exchange receives written notice of an issuer's intent to withdraw its ETP from the Incentive Program, or an LMM's intent to withdraw from its ETP assignment(s) in the Incentive Program, and, in each case, the intended withdrawal date, if provided; and (v) the amount of the Optional Incentive Fee for each ETP.[25] This page will also include a fair and balanced description of the Incentive Program, including: (i) a description of the Incentive Program's operation as a pilot, including the effective date thereof; (ii) the potential benefits that may be realized by an ETP's participation in the Incentive Program; (iii) the potential risks that may be attendant with an ETP's participation in the Incentive Program; (iv) the potential impact resulting from an ETP's entry into and exit from the Incentive Program; and (v) how interested parties can request additional information regarding the Incentive Program and/or the ETPs participating therein.[26]

Under proposed NYSE Arca Equities Rule 8.800(b)(7), an issuer of an ETP that is approved to participate in the Incentive Program will be required to issue a press release to the public when an ETP commences or ceases participation in the Incentive Program. The press release will be in a form and manner prescribed by the Exchange, and if practicable, will be issued at least two days before the ETP commences or ceases participation in the Incentive Program.[27] The issuer also will be required to dedicate space on its Web site, or, if it does not have a Web site, on the Web site of the adviser or sponsor of the ETP, to (i) include any such press releases and (ii) provide a hyperlink to the dedicated page on the

[13] The Exchange maintains a list of ETPs that have suspended the issuance of new shares, which is available at *https://etp.nyx.com/en/trading-information/us/funds-closed-creation.*

[14] *See* proposed NYSE Arca Equities Rule 8.800(a).

[15] *See* proposed NYSE Arca Equities Rule 8.800(b)(1).

[16] *Id.*

[17] *Id.*

[18] *See* Notice, *supra* note 4, at 21685.

[19] *See* proposed NYSE Arca Equities Rule 8.800(b)(2).

[20] The written solicitation will be included in the ''Green Sheet,'' which is the common term for an email communication sent by Exchange staff members to all qualified LMMs prior to an LMM selection. The Green Sheet includes, among other things, the name, symbol and description of the ETP(s) as well as the name of the issuer and a link to the ETP prospectus. A qualified LMM must complete the application for a specific ETP or group of ETPs. *See* Notice, *supra* note 4, at 21685–6, n.15.

[21] *See* proposed NYSE Arca Equities Rule 8.800(b)(3). *See also* Section I(C) *infra* for further discussion of the Optional Incentive Fee.

[22] *See* proposed NYSE Arca Equities Rule 8.800(b)(5). An LMM may provide material to the Exchange staff, which may include a corporate overview of the LMM and the trading experience of its personnel. Exchange staff will meet with representatives of each LMM if requested by the LMM, and no more than three representatives of each LMM may participate in the meeting, each of whom must be employees of the LMM, and one of whom must be the individual trader of the LMM who is proposed to trade the ETP. If the LMM is unavailable to appear in person, a telephone interview with that LMM would be acceptable. Meetings will normally be held at the Exchange, unless the Exchange agrees that they may be held elsewhere. *Id.*

[23] *Id.*

[24] *Id.* Proposed NYSE Arca Equities Rule 8.800(b)(5) is modeled in part on New York Stock Exchange Rule 103B(III)(B)(1), which governs Designated Market Maker unit assignments for equities listed on the NYSE. *See* Notice, *supra* note 4, at 21686, n.20.

[25] *See* proposed NYSE Arca Equities Rule 8.800(b)(6). *See* also Amendment No. 2, *supra* note 6.

[26] *See* proposed NYSE Arca Equities Rule 8.800(b)(6).

[27] *See* proposed NYSE Arca Equities Rule 8.800(b)(7). The issuer's press release will be required to include language describing, for example, that while the impact of participation in or exit from the Incentive Program, which is optional, cannot be fully understood until objective observations can be made in the context of the Incentive Program, potential impacts on the market quality of the issuer's ETP may result, including with respect to the average spread and average quoted size for the ETP. *See* Notice, *supra* note 4, at 21686, n.21.

Exchange's Web site that describes the Incentive Program.[28]

C. Optional Incentive Fee

The Exchange proposes to amend its Listing Fee Schedule to provide that the Optional Incentive Fee under NYSE Arca Rule 8.800 may initially range from $10,000 to $40,000, as determined by the issuer of an ETP.[29] The Optional Incentive Fee for each ETP will be paid by the issuer to the Exchange in quarterly installments at the beginning of each quarter and prorated if the issuer commences participation for an ETP in the Incentive Program after the beginning of a quarter.[30] If an LMM does not meet its performance standards (as described below) for an ETP in any given month in such quarter, the issuer would not receive any refund or credit from the Exchange following the end of the quarter.[31] If the ETP has a sponsor, the sponsor may pay the Optional Incentive Fee to the Exchange.[32]

D. Incentive Program LMM Performance Standards

Proposed NYSE Arca Equities Rule 8.800(c) describes the proposed Incentive Program LMM performance standards (''Incentive Program LMM Performance Standards'') that will apply to an LMM for each ETP participating in the Incentive Program to which it is assigned. An LMM in the Incentive Program also will remain obligated to satisfy the general requirements of NYSE Arca Equities Rule 7.23.[33]

Pursuant to proposed NYSE Arca Equities Rule 8.800(c)(2), an LMM will be subject to a ''Market-Wide Requirement.'' Specifically, an LMM will be required to maintain quotes or orders at the National Best Bid or Offer (''NBBO'') or better (''Inside'') during the month during Core Trading Hours in accordance with the following maximum width and minimum depth thresholds, which are provided in proposed Commentary .01 to Rule 8.800.[34]

Daily share volume	Quote type	Requirement	Prices ($)			
			0–4.99	5–14.99	15–49.99	50 or more
0–4,999	Inside	Width (%)	15.00	6.00	5.00	4.00
		Depth (sh)	700	400	300	200
5,000–24,999	Inside	Width (%)	7.00	3.00	2.00	1.50
		Depth (sh)	700	400	300	200
25,000–74,999	Inside	Width (%)	5.00	1.50	1.00	0.70
		Depth (sh)	700	400	300	200
75,000–199,999	Inside	Width (%)	3.00	1.00	0.50	0.30
		Depth (sh)	700	400	300	200
200,000–499,999	Inside	Width (%)	2.00	0.60	0.30	0.20
		Depth (sh)	700	400	300	200
500,000 or more	Inside	Width (%)	1.00	0.30	0.20	0.10
		Depth (sh)	2000	1000	500	300

However, the Market-Wide Requirement will not apply to an LMM if these thresholds are otherwise met by quotes or orders of all market participants across all markets trading the ETP.[35]

Pursuant to proposed NYSE Arca Equities Rule 8.800(c)(3), an LMM also will be subject to a NYSE Arca-specific requirement, which can be satisfied in one of two ways. First, an LMM may satisfy the ''Time-at-the-Inside Requirement'' under proposed NYSE Arca Equities Rule 8.800(c)(3)(A), pursuant to which an LMM will be required to maintain quotes or orders on the Exchange at the NBBO or better at least 15% of the time when quotes may be entered during Core Trading Hours each trading day, as averaged over the course of a month.[36] Alternatively, an LMM may choose to satisfy the ''Size-Setting NBBO Requirement'' under proposed NYSE Arca Equities Rule 8.800(c)(3)(B), pursuant to which an LMM will be required to maintain ''size-setting'' quotes or orders on the Exchange, as compared to trading interest on other markets, at the NBBO or better at least 25% of the time when quotes may be entered during Core Trading Hours each trading day, as averaged over the course of a month; provided, however, that the Size-Setting NBBO Requirement will not apply to an LMM if this threshold is otherwise met by quotes or orders of other market participants on NYSE Arca.[37]

Finally, under proposed NYSE Arca Equities Rule 8.800(c)(4), for at least 90% of the time when quotes may be entered during Core Trading Hours each trading day, as averaged over the course of a month, an LMM will be required to maintain (A) at least 2,500 shares of attributable, displayed posted buy liquidity on the Exchange that is priced no more than 2% away from the NBB for the particular ETP, and (B) at least

[28] *See* proposed NYSE Arca Equities Rule 8.800(b)(7). The disclosure requirements set forth in the proposal would be in addition to, and would not supersede, the prospectus disclosure requirements under the Securities Act of 1933 or the Investment Company Act of 1940. *See* Notice, *supra* note 4, at 21686, n.22.

[29] *See* proposed Listing Fee Schedule. Optional Incentive Fees paid by an issuer will be credited to the Exchange's general revenues. An issuer participating in the Incentive Program will still be required to pay applicable listing and annual fees. *See* Notice, *supra* note 4, at 21686, n.16.

[30] *See* proposed Listing Fee Schedule.

[31] *Id.*

[32] *Id.* The term ''sponsor'' means the registered investment adviser that provides investment management services to an ETP or any of such investment adviser's parents or subsidiaries. *Id.*

[33] *See* proposed NYSE Arca Equities Rule 8.800(c)(1). *See also* Amendment No. 2, *supra* note 6.

[34] *See* proposed NYSE Arca Equities Rule 8.800(c)(2). Proposed Commentary .01 to NYSE Arca Equities Rule 8.800 provides that (i) the spread thresholds will be calculated as the time-weighted average throughout the trading day and then averaged, by day, across the month and (ii) the depth thresholds will be calculated as the average of (a) the average time-weighted bid depth and (b) the average time-weighted ask depth.

[35] *Id.*

[36] Proposed Commentary .01 to NYSE Arca Equities Rule 8.800 provides that the Time-at-the-Inside Requirement will be calculated as the average of (a) the percentage of time the LMM has a bid on the Exchange at the National Best Bid (''NBB'') and (b) the percentage of time the LMM has an offer on the Exchange at the National Best Offer (''NBO'').

[37] Proposed Commentary .01 to NYSE Arca Equities Rule 8.800 provides that: (i) The Size-Setting NBBO Requirement will be calculated throughout the trading day and then averaged, by day, across the month; (ii) quotes and orders of all market participants across all markets trading the security will be considered when calculating the Size-Setting NBBO Requirement; (iii) a quote or order will be considered ''size-setting'' if it is at the NBB or NBO; (iv) if multiple quotes or orders exist at the same price, the quote or order with the largest size will be considered ''size-setting;'' and (v) if multiple quotes or orders exist at the same price and the same size, the quote or order with the earliest entry time will be considered ''size-setting.''

2,500 shares of attributable, displayed posted offer liquidity on the Exchange that is priced no more than 2% away from the NBO for the particular ETP.

Proposed Commentary .01 to NYSE Arca Equities Rule 8.800 provides that only displayed quotes and orders will be considered for purposes of the Incentive Program LMM Performance Standards.

E. LMM Payment

Proposed NYSE Arca Equities Rule 8.800(d) provides that the Exchange will credit an LMM for an ''LMM Payment,'' which will be determined by the Exchange and set forth in the Trading Fee Schedule. An LMM participating in the Incentive Program would not be entitled to an LMM Payment unless and until it meets or exceeds the Incentive Program LMM Performance Standards for an assigned ETP, as determined by the Exchange.[38] LMM Payments will be paid by the Exchange from its general revenues.[39]

The Exchange proposes to amend its Trading Fee Schedule to provide that at the end of each quarter, the Exchange will credit an LMM an LMM Payment for each month during such quarter that the LMM meets or exceeds its Incentive Program LMM Performance Standards for an assigned ETP. If an LMM does not meet or exceed the Incentive Program LMM Performance Standards for an assigned ETP for a particular month, or the ETP is withdrawn from the Incentive Program, then the LMM Payment will be zero for such month.[40] The amount of the LMM Payment for a particular month will not exceed ⅓ of the quarterly Optional Incentive Fee, as determined by the issuer, less an Exchange administration fee of 5%.[41] LMMs participating in the Fixed Incentive Program will be subject to the transaction fees and credits applicable to ETP Holders and Market Makers for transactions in their assigned ETPs during the quarter instead of the LMM transaction fees and credits.[42] If an issuer does not pay its quarterly installments to the Exchange on time and the ETP continues to be listed, the Exchange will continue to credit the LMM if the LMM meets its Incentive Program LMM Performance Standards.[43]

F. Withdrawal and Reallocation

Proposed NYSE Arca Equities Rule 8.800(e) describes the circumstances for withdrawal from the Incentive Program. First, if an ETP no longer meets continuing listing standards, suspends the creation and/or redemption of shares, or liquidates, it will be automatically withdrawn from the Incentive Program as of the ETP suspension date.[44]

Second, the Exchange, in its discretion, may allow an issuer to withdraw an ETP from the Incentive Program before the end of the pilot period if the assigned LMM is unable to meet its Incentive Program LMM Performance Standards for any two of the three months of a quarter or for five months during the pilot period and no other qualified ETP Holder was able to take over the assignment.[45]

Third, an LMM may withdraw from all of its ETP assignments in the Incentive Program, or the Exchange, in its discretion, may allow an LMM to withdraw from a particular ETP before the end of the pilot period if the Exchange determines that there are extraneous circumstances that prevent the LMM from meeting its Incentive Program LMM Performance Standards for such ETP that do not affect its other ETP assignments in the Incentive Program.[46] In either case, the LMM's ETP(s) will be reallocated in accordance with proposed NYSE Arca Equities Rule 8.800(f) (described below).

Fourth, if an ETP maintains a CADV of one million shares or more for three consecutive months, it will be automatically withdrawn from the Incentive Program within one month thereafter.[47] If after such automatic withdrawal the ETP fails to maintain a CADV of one million shares or more for three consecutive months, the issuer of the ETP may reapply for the Incentive Program one month thereafter.[48]

Finally, if the issuer is not current in all payments due to the Exchange for two consecutive quarters, its ETP will be automatically terminated from the Incentive Program.[49]

Proposed NYSE Arca Equities Rule 8.800(f) describes the LMM reallocation process. If the LMM for a particular ETP does not meet or exceed its Incentive Program LMM Performance Standards for any two of the three months of a quarter or for five months during the pilot period, or chooses to withdraw from the Incentive Program, and at least one other qualified Market Maker has agreed to become the assigned LMM under the Incentive Program, then the ETP will be reallocated and another LMM will be solicited and assigned in accordance with proposed NYSE Arca Equities Rule 8.800(b).[50] The reallocation process will be completed no sooner than the end of the current quarter and no later than the end of the following quarter.[51]

G. Implementation of Pilot

The Incentive Program will be offered to issuers from the date of implementation, which will occur no later than 90 days after Commission approval of the filing, until one calendar year after implementation.[52] During the pilot period, the Exchange will assess the Incentive Program and may expand the criteria for ETPs that are eligible to participate, for example, to permit issuers to include more than five ETPs that were listed on the Exchange before the pilot period commenced.[53] At the end of the pilot period, the Exchange will determine whether to continue or discontinue the Incentive Program or make it permanent.[54]

During the Incentive Program, the Exchange will provide the Commission with certain market quality reports each month, which will also be posted on the Exchange's Web site.[55] Such reports will include the Exchange's analysis regarding the Incentive Program and whether it is achieving its goals, as well as market quality data such as (for all ETPs listed as of the date of implementation of the Incentive Program and listed during the pilot period for comparative purposes, including comparable ETPs that are listed on the Exchange but not participating in the Incentive Program):

[38] *See* Notice, *supra* note 4, at 21687.

[39] *Id.*

[40] *See* proposed Trading Fee Schedule.

[41] *Id.*

[42] *Id.* The Exchange currently provides LMMs with an opportunity to receive incrementally higher transaction credits and incur incrementally lower transaction fees (''LMM Rates'') compared to standard liquidity maker-taker rates (''Standard Rates''). *See* Notice, *supra* note 4, at 21682. LMMs in the Incentive Program would be subject to the Standard Rates instead of the LMM Rates. *Id.* at 21687.

[43] *See* proposed Trading Fee Schedule.

[44] *See* proposed NYSE Arca Equities Rule 8.800(e)(1).

[45] *See* proposed NYSE Arca Equities Rule 8.800(e)(2).

[46] *See* proposed NYSE Arca Equities Rule 8.800(e)(3).

[47] *See* proposed NYSE Arca Equities Rule 8.800(e)(4).

[48] *Id.*

[49] *See* proposed NYSE Arca Equities Rule 8.800(e)(5).

[50] *See* proposed NYSE Arca Equities Rule 8.800(f).

[51] *Id.*

[52] *See* Notice, *supra* note 4, at 21688.

[53] *Id.* The Commission notes that any modifications to the terms of the proposal would require a rule filing with the Commission pursuant to Section 19(b) of the Exchange Act and Rule 19b–4 thereunder.

[54] The Commission notes that any proposed continuance of the Program or proposal to make the Program permanent would require a rule filing with the Commission pursuant to Section 19(b) of the Exchange Act and Rule 19b–4 thereunder.

[55] *See* Notice, *supra* note 4, at 21688.

volume (CADV and NYSE Arca average daily volume); NBBO bid/ask spread differentials; LMM participation rates; NYSE Arca market share; LMM time spent at the inside; LMM time spent within $0.03 of the inside; percent of time NYSE Arca had the best price with the best size; LMM quoted spread; LMM quoted depth; and Rule 605 statistics (one-month delay).[56] These reports will also compare, to the extent practicable, ETPs before and after they are in the Incentive Program, and will further provide data and analysis about the market quality of ETPs that exceed the one million CADV threshold and ''graduate,'' or are otherwise withdrawn or terminated from, the Incentive Program.[57] In connection with the proposal, the Exchange will provide other data and information related to the Incentive Program as may be periodically requested by the Commission.[58] In addition, the Exchange states that issuers may utilize ArcaVision to analyze and replicate data on their own.[59]

H. Surveillance

The Exchange represents that its surveillance procedures will be adequate to properly monitor the trading of ETPs participating in the Incentive Program on the Exchange during all trading sessions and to detect and deter violations of Exchange rules and applicable federal securities laws.[60] The Exchange states that trading of the ETPs through the Exchange will be subject to FINRA's surveillance procedures for derivative products,[61] and that the Exchange may obtain information via the Intermarket Surveillance Group (''ISG'') from other exchanges that are members or affiliates of the ISG; and from issuers and public and non-public data sources such as, for example, Bloomberg.[62]

II. Summary of Comment Letters

The Commission received two comment letters in support of the proposed rule change.[63] One commenter states that it supports regulatory changes that result in more efficient markets for issuers of ETPs and thus supports the Incentive Program.[64] This commenter encourages programs that make it possible for all firms to attempt to list new and innovative securities in the marketplace and have an opportunity to receive adequate support from the market making community, as the commenter believes such developments directly benefit new entrants, existing small competitors, and investors.[65] This commenter emphasizes that the program is being implemented as a pilot and thus will be fairly easy for either the Exchange or the Commission to alter or terminate with little or no negative consequences to the marketplace.[66] Further, the commenter states its observation that the current market model does not encourage broker/dealers to assume the additional responsibilities of being an LMM and that this proposal should encourage more market makers to become LMMs.[67] The commenter suggests that the success of the program should be measured by the increase in the number of firms willing to act as an LMM under the proposal, rather than how tight spreads are in ETPs subject to the pilot.[68]

Another commenter points out that several academic studies have found that the imposition of market making obligations in exchange for certain privileges tends to enhance market quality, resulting in improved economic efficiency rather than mere wealth transfers.[69] This commenter states that, to the extent the Incentive Program promotes the adoption of trading obligations that enhance liquidity, it is likely to promote economic efficiency.[70] The commenter states that while there may be some concerns that payments to market makers represent subsidies, this should not necessarily be viewed negatively, as studies have shown that the subsidization of liquidity can improve economic welfare and increase ''the size of the pie.''[71] The commenter further argues that a direct subsidy in the form of regular payments from issuers/sponsors to market makers, such as the one proposed pursuant to the Incentive Program, may have an advantage over traditional indirect subsidies provided to market makers (*e.g.,* time or information advantages, order flow allocation, etc.), which have historically been subject to abuse, insofar as the fees and payments under the Incentive Program are transparent and flow through and are monitored by the Exchange.[72] The commenter further states that the specificity of the eligibility criteria for LMMs in the proposal should mitigate the concern that having just one market maker participant in the Incentive Program would be detrimental to competition.[73] Similarly, this commenter recognizes that manipulation is a concern with respect to this proposal, but states that the administration and monitoring of the Incentive Program by the Exchange is a mitigating factor.[74]

III. Discussion and Commission Findings

The Commission has carefully considered the proposed rule change, as modified by Amendment Nos. 1 and 2 thereto, and finds that the proposed rule change, as modified by Amendment

[56] *Id. See also* Amendment No. 2, *supra* note 6.

[57] *See* Amendment No. 2, *supra* note 6.

[58] *See* Notice, *supra* note 4, at 21688.

[59] *Id.* NYSE Arca provides ArcaVision free of charge to the public via the Web site *www.ArcaVision.com.* According to the Exchange, ArcaVision offers a significant amount of trading data and market quality statistics for every Regulation NMS equity security traded in the United States, including all ETPs. Publicly available reports within ArcaVision, which include relevant comparative data, are the Symbol Summary, Symbol Analytics, Volume Comparison and Quotation Comparison reports, among others. In addition, users can create the reports on a per-symbol basis over a flexible time frame and can also take advantage of predefined symbol sets based on type of ETP or issuer. Users can also create their own symbol lists. The Exchange states that ArcaVision allows an ETP issuer to see additional information specific to its LMM and other Market Makers in each ETP via the ''ArcaVision Market Maker Summary'' reporting mechanism. *Id.*

[60] *See* Notice, *supra* note 4, at 21690.

[61] FINRA surveils trading on the Exchange, including ETP trading, pursuant to a Regulatory Services Agreement (''RSA''). The Exchange is responsible for FINRA's performance under this RSA. *Id.* at 21689, n.29

[62] *Id.* at 21690.

[63] *See* USCF Letter and Dolgopolov Letter, *supra* note 5.

[64] *See* USCF Letter, *supra* note 5, at 1.

[65] *Id.* at 2.

[66] *Id.* at 1.

[67] *Id.* at 1–2.

[68] *Id.* at 2.

[69] *See* Dolgopolov Letter, *supra* note 5, at 3, citing to the following studies: Amber Anand & Daniel G. Weaver, *The Value of the Specialist: Empirical Evidence from the CBOE,* 9 J. FIN. MKTS. 100, 102–04 (2006); Rafi Eldor *et al., The Contribution of Market Makers to Liquidity and Efficiency of Options Trading in Electronic Markets,* 30 J. BANKING & FIN. 2025, 2025, 2029–31 (2006); M. Nimalendran & Giovanni Petrella, *Do Thinly-Traded Stocks Benefit from Specialist Intervention?,* 27 J. BANKING & FIN. 1823, 1829–30, 1851–52 (2003); Marios A. Panayides, *Affirmative Obligations and Market Making with Inventory,* 86 J. FIN. ECON. 513, 513 (2007); and Narayan Y. Naik & Pradeep K. Yadav, *Trading Costs of Public Investors with Obligatory and Voluntary Market-Making: Evidence from Market Reforms* 1, 17, 35 (Eur. Fin. Ass'n, Annual Conference Paper No. 408, 2003), available at *http://ssrn.com/abstract=424982.*

[70] *See* Dolgopolov Letter, *supra* note 5, at 5.

[71] *See* Dolgopolov Letter, *supra* note 5, at 2, citing the following studies: Kumar Venkataraman & Andrew C. Waisburd, *The Value of the Designated Market Maker,* 42 J. FIN. & QUANT. ANALYSIS 735 (2007); Kalman J. Cohen *et al., The Impact of Designated Market Makers on Security Prices,* 1 J. BANKING & FIN. 219, 245 (1977); Jennifer Huang & Jiang Wang, *Market Liquidity, Asset Prices, and Welfare,* 95 J. FIN. ECON. 107, 109 (2010); Wen Mao & Michael S. Pagano, *Specialists as Risk Managers: The Competition Between Intermediated and Non-Intermediated Markets,* 35 J. BANKING & FIN. 51, 64 (2011); and Johannes A. Skjeltorp & Bernt Arne Ødegaard, Why Do Listed Firms Pay for Market Making in Their Own Stock? 16, 30 (May 2012) (unpublished manuscript) (on file with author), available at *http://ssrn.com/abstract=1944057*).

[72] *Id.* at 2–3.

[73] *Id.* at 4.

[74] *Id.* at 4–5.

Nos. 1 and 2 thereto, is consistent with the requirements of the Act and the rules and regulations thereunder applicable to national securities exchanges. In particular, as discussed below, the Commission finds that the proposed rule change is consistent with Section 6(b)(4) of the Act,[75] which requires that the rules of a national securities exchange provide for the equitable allocation of reasonable dues, fees, and other charges among its members and issuers and other persons using its facilities, and with Section 6(b)(5) of the Act,[76] which requires, among other things, that the rules of a national securities exchange be designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest, and that the rules not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers. Further, as required by Section 3(f) of the Act, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation.[77]

The Incentive Program, as proposed to be implemented on a pilot basis, is designed to enhance the market quality for certain lower volume ETPs participating in the program by incentivizing Market Makers to take LMM assignments in such ETPs by offering an alternative fee structure for such LMMs. As proposed by the Exchange, to be eligible to receive quarterly LMM Payments, an LMM participating in the program will be required to comply with the Incentive Program LMM Performance Standards, which are higher than the standard quoting requirements applicable to Market Makers on the Exchange. Specifically, in addition to satisfying the requirements of NYSE Arca Equities Rule 7.23, and subject to certain exceptions as further described above, an LMM participating in the program will be required to comply with the Market-Wide Requirement, and also with either the Time-at-the-Inside Requirement or the Size-Setting NBBO Requirement. In addition, an LMM participating in the Incentive Program must quote at least 2,500 shares of attributable, displayed liquidity within 2% of the NBB or NBO 90% of the time during Core Trading Hours. An LMM will receive an LMM Payment in an amount not to exceed ⅓ of the quarterly Optional Incentive Fee, less an Exchange administration fee of 5%, for each month the LMM meets or exceeds these heightened performance standards. Thus, the proposal is designed to incentivize LMMs participating in the Incentive Program to quote more often, and in greater quoted size, at the NBBO by conditioning the LMM Payment on whether an LMM meets or exceeds the Incentive Program LMM Performance Standards, including the Market-Wide Requirement, the Time-at-the Inside Requirement or, alternatively, the Size-Setting NBBO Requirement, and the additional requirement that an LMM must quote at least 2,500 shares of attributable, displayed liquidity within 2% of the NBB or NBO 90% of the time during Core Trading Hours. As a result, the proposal has the potential to improve the market quality of the ETPs that participate in the Incentive Program by encouraging LMMs to provide liquidity in such ETPs consistent with the Incentive Program LMM Performance Standards.[78] This potential improved market quality, were it to occur, could benefit investors in the form of enhanced liquidity, narrowed spreads, and reduced transaction costs.

In addition, because the quoted bid-ask spread in a security represents one of the main drivers of transaction costs for investors, and because high price volatility should generally deter investors from trading low-liquidity ETPs, the Incentive Program, were the potential benefits of the program to occur, should facilitate a more-efficient and less-uncertain trading environment for investors.[79] Furthermore, were the potential benefits of the Incentive Program to occur, improving the liquidity of certain low-volume ETPs may lead to both an overall increase in ETP trading volume and a redistribution of trading volume toward lower-volume ETPs that would not otherwise attract sufficient liquidity to successfully participate in the market.

While the Commission believes that the Incentive Program has the potential to improve market quality of the ETPs participating in the program, the Commission is concerned about unintended consequences of the Incentive Program. For example, the Incentive Program could have the potential to distort market forces because the Incentive Program may act to artificially influence trading in ETPs that otherwise would not be traded. Similarly, the Commission recognizes concerns about the potential negative impact on an ETP participating in the program, such as reduced liquidity and wider spreads, when an ETP is withdrawn or terminated from the Incentive Program. While the Commission is mindful of these concerns, the Commission believes, for the reasons described below, that certain aspects of the Incentive Program could help mitigate these concerns.

First, the proposal contains disclosure provisions that will help to alert and educate potential and existing investors in the ETPs participating in the Program about the program. Specifically, the Exchange will disclose on its Web site the following information: (i) the ETPs participating in the Incentive Program and the LMM assigned to each participating ETP; (ii) the date a particular ETP begins participating or ceases participating in the Incentive Program; (iii) the date the Exchange receives written notice of an issuer's intent to withdraw its ETP from the Incentive Program, or an LMM's intent to withdraw from its ETP assignment(s) in the Incentive Program, and, in each case, the intended withdrawal date, if

[75] 15 U.S.C. 78f(b)(4).

[76] 15 U.S.C. 78f(b)(5).

[77] *See* 15 U.S.C. 78c(f).

[78] The Exchange states that when there is an LMM assigned to a security listed on NYSE Arca, long-term investors trading on the Exchange in the secondary market likely experience enhanced market quality compared to similar securities for which there are no LMMs assigned. *See* Notice, *supra* note 4, at 21683. The Exchange further states that in the fourth quarter of 2012, there were 609 ETPs listed on NYSE Arca that traded less than 10,000 shares CADV, and of those ETPs, 567 had LMMs while 42 did not, and the average spread for the ETPs with LMMs was 0.79% and the average quote size was 3,014 shares, while the average spread for the ETPs without LMMs was 11.52% and the average quote size was 1,655 shares. *Id.* In addition, the Exchange states that during the same time period, there were 410 ETPs listed on NYSE Arca that traded between 10,000 shares and 100,000 shares CADV, and of those ETPs, 396 had LMMs while 14 did not, and the average spread for the ETPs with LMMs was 0.23% and the average quote size was 6,643 shares, while the average spread for ETPs without LMMs was 0.36% and the average quote size was 2,613 shares. *Id.* The Exchange maintains that these observations are consistent over longer time periods and that there has been a greater variance in market quality for ETPs without LMMs. *Id.* at 21683–4.

[79] Transaction costs are generally defined as the penalty that an investor pays for transacting. Transaction costs have four components: commissions; bid/ask spread; market impact; and opportunity cost. *See* Grinold, Kahn. *Active Portfolio Management,* Second Edition, Chapter 16. An increase in bid-ask spreads will inevitably increase the transaction costs of an investor. In addition, transactions in low-liquidity securities have a higher market impact when compared to other more liquid securities. *See* Albert Kyle's (1985) measure of market impact (Kyle's Lambda), defining an inverse relationship between volume and price impact. Therefore, the lower the volume of the ETP or stock, the higher the market impact of any transaction in that stock. This last effect acts as a disincentive to trading that security. Therefore, an environment where an ETP trades more often and with a larger number of shares will reduce transaction costs both through the narrowing of spreads and lower market impact.

provided; and (iii) the amount of the Optional Incentive Fee for each ETP. The Exchange also will include on its Web site a fair and balanced description of the Incentive Program, including a description of the potential benefits and risks that may be attendant with an ETP's participation in the program. Furthermore, an issuer of an ETP that is approved to participate in the Incentive Program will be required to issue a press release to the public when an ETP commences or ceases participation in the Incentive Program, to post such press release on its Web site, and to provide on its Web site a hyperlink to the Exchange's Web page describing the Incentive Program. This disclosure will help to inform investors and other market participants which ETPs are participating in the Incentive Program, which LMMs are assigned to each ETP, the amount of Optional Incentive Fee an issuer will incur as a result of participating in the Incentive Program, the maximum amount of LMM Payments an LMM could potentially receive from the Exchange under the Incentive Program, and the potential benefits and risks of the program. A wide variety of ETPs are currently listed and trading today, and the Commission believes that such disclosure could be helpful for investors and other market participants to discern which ETPs listed on the Exchange are and are not subject to the Incentive Program and to make informed investment decisions with respect to ETPs.[80]

Second, the Incentive Program is targeted at a subset of ETPs, namely those ETPs that are generally less liquid and which the Exchange believes might benefit most from the Incentive Program. Specifically, as proposed, ETPs that are otherwise eligible for the Incentive Program will not be eligible if they have a CADV of more than 1,000,000 shares for three consecutive months. Likewise, the Incentive Program will terminate with respect to a particular ETP if the ETP sustains a CADV of 1,000,000 shares or more for three consecutive months.

Finally, as proposed by the Exchange, the Incentive Program will be limited to a one-year pilot. The Commission believes that it is important to implement the Incentive Program as a pilot. Operating the Incentive Program as a pilot will allow assessment of whether the Incentive Program is in fact achieving its goal of improving the market quality of ETPs by incentivizing Market Makers to take LMM assignments, prior to any proposal or determination to make the program permanent.[81] In addition, approval on a pilot basis will allow the assessment, prior to any proposal or determination to make the program permanent, of whether the Incentive Program has any unintended impact on the participating ETPs, securities not participating in the program, or the market or market participants generally.

The Exchange has represented that during the pilot it will submit monthly reports to the Commission about market quality in respect of the Incentive Program and that these reports will be posted on the Exchange's public Web site. The Exchange has represented that such reports will include the Exchange's analysis regarding the Incentive Program and whether it is achieving its goals, as well as market quality data for all ETPs listed as of the date of implementation of the Incentive Program and listed during the pilot period (for comparative purposes, including comparable ETPs that are listed on the Exchange but not participating in the Incentive Program) such as volume (CADV and NYSE Arca average daily volume), NBBO bid/ask spread differentials, LMM participation rates, NYSE Arca market share, LMM time spent at the inside, LMM time spent within $0.03 of the inside, percent of time NYSE Arca had the best price with the best size, LMM quoted spread, LMM quoted depth, and Rule 605 statistics (one-month delay). In addition, the Exchange has represented that it will provide in the monthly public report to the Commission data and analysis on the market quality of ETPs after they exceed the one million CADV threshold and ''graduate'' from the program or are otherwise withdrawn or terminated from the program. The Exchange also has represented that it will provide to the Commission and any other data and information related to the Incentive Program as may be periodically requested by the Commission in connection with the proposal. In addition, the Exchange has represented that issuers may utilize ArcaVision to analyze and replicate data on their own.[82] This information will help the Commission, the Exchange, and other interested persons to evaluate whether the Incentive Program has resulted in the intended benefits it is designed to achieve, any unintended consequences resulting from the Incentive Program, and the extent to which the Incentive Program alleviates or aggravates the concerns the Commission has noted, including previously-stated Commission concerns relating to issuer payments to market makers.[83]

For example, the Exchange and the Commission will look to assess what impact, if any, there is on the market quality of ETPs that withdraw or are otherwise terminated from the Incentive Program. One way for an ETP to be terminated from the Incentive Program is if it exceeds the 1,000,000 CADV threshold included within the rules.[84] The Commission recognizes that the Incentive Program may not, in the one-year pilot period, produce sufficient data (*i.e.,* a large number of ETPs that enter and exit the Incentive Program) to allow a full assessment of whether termination (or withdrawal) of an ETP from the program has resulted in any unintended consequences on the market quality of the ETP or otherwise. However, the Commission believes that the proposal strikes a reasonable balance between (i) setting the threshold for ''graduation'' from the Incentive Program high enough to encourage participation in the program and (ii) setting the threshold low enough to have a sufficient number of ETPs graduate from the Incentive Program within the pilot period so that the Exchange, the Commission, and other interested persons can assess the impact, if any, of the Incentive Program, including ''graduation'' of ETPs from the program.

Furthermore, the pilot structure of the Incentive Program will provide information to help determine whether any provisions of the Incentive Program should be modified. For example, based on data from the pilot, the Exchange may determine that the 1,000,000 CADV termination threshold is not an appropriate threshold on which to base eligibility for the program or that the program should be time-limited.

The Commission believes that the design of the Incentive Program and the public disclosure requirements, coupled with implementation of the proposal on a pilot basis, should help mitigate potential concerns the Commission has noted above relating to any unintended or negative effects of the Incentive

[80] The concurrent exemptive relief the Commission is issuing today from Rule 102 under Regulation M concerning the Incentive Program also contains additional disclosure requirements. *See* Securities Exchange Act Release No. 69707 (June 6, 2013), *supra* note 7.

[81] The Exchange would be required to file with the Commission any proposal to extend the Incentive Program beyond the pilot period or to make the program permanent pursuant to Section 19(b) of the Exchange Act and the rules and regulations thereunder. Such a filing would be published for comment in the **Federal Register** pursuant to Section 19(b) and Rule 19b–4.

[82] *See supra* note 59 and accompanying text.

[83] *See infra* notes 86–89 and accompanying text.

[84] *See* proposed NYSE Arca Equities Rule 8.800(e)(4).

Program on the ETP market and investors.

The Commission has previously expressed concerns relating to payments by issuers to market makers. Financial Industry Regulatory Authority (''FINRA'') Rule 5250 (formerly NASD Rule 2460) prohibits FINRA members and their associated persons from directly or indirectly accepting any payment from an issuer for acting as a market maker.[85] FINRA Rule 5250 was implemented, in part, to address concerns about issuers paying market makers, directly or indirectly, to improperly influence the price of an issuer's stock and because of conflict of interest concerns between issuers and market makers.[86] FINRA Rule 5250 was designed to preserve ''the integrity of the marketplace by ensuring that quotations accurately reflect a broker-dealer's interest in buying or selling a security.'' [87] Specifically, in the NASD Rule 2460 Approval Order, the Commission found that the

''decision by a firm to make a market in a given security and the question of price generally are dependent on a number of factors, including, among others, supply and demand, the firm's expectations toward the market, its current inventory position, and exposure to risk and competition. This decision should not be influenced by payments to the member from issuers or promoters. Public investors expect broker-dealers' quotations to be based on the factors described above. If payments to broker-dealers by promoters and issuers were permitted, investors would not be able to ascertain which quotations in the marketplace are based on actual interest and which quotations are supported by issuers or promoters. This structure would harm investor confidence in the overall integrity of the marketplace.''[88]

The Commission also added that ''such payments may be viewed as a conflict of interest since they may influence the member's decision as to whether to quote or make a market in a security and, thereafter, the prices that the member would quote.''[89]

The Commission believes that a number of aspects of the Incentive Program mitigate the concerns that FINRA Rule 5250 was designed to address. First, the Commission believes that the terms of the Incentive Program are generally objective, clear, and transparent. The standards for the Incentive Program are set forth in proposed NYSE Arca Equities Rule 8.800 and the Exchange's Listing Fee Schedule and Trading Fee Schedule (further described above) [90] and describe the ETP eligibility criteria, application and assignment process, fee and payment structure, performance standards that an LMM must meet and maintain to secure an LMM Payment, withdrawal and termination standards, and LMM reallocation process. These requirements apply to all ETPs, issuers, and LMMs participating in the Incentive Program.

Second, the Exchange also will provide notification on its public Web site regarding the various aspects of the Incentive Program. As discussed above, this disclosure will include: (i) the ETPs participating in the Incentive Program and the LMM assigned to each participating ETP; (ii) the date a particular ETP begins participating or ceases participating in the Incentive Program; (iii) the date the Exchange receives written notice of an issuer's intent to withdraw its ETP from the Incentive Program, or an LMM's intent to withdraw from its ETP assignment(s) in the Incentive Program, and, in each case, the intended withdrawal date, if provided; (iv) the amount of the Optional Incentive Fee for each ETP; and (v) a fair and balanced description of the Incentive Program, including the potential benefits and risks that may be attendant with an ETP's participation in the program. In addition, an issuer of an ETP participating in the Incentive Program will be required to issue a press release when an ETP commences or ceases participation in the Incentive Program, to post such press release on its Web site, and to provide on its Web site a hyperlink to the Exchange's Web page describing the Incentive Program.

And third, ETPs participating in the Incentive Program will be traded on the Exchange, which is a regulated market, pursuant to the current trading and reporting rules of the Exchange, and pursuant to the Exchange's established market surveillance and trade monitoring procedures. The Exchange will administer the application and acceptance of the ETPs and LMMs into the Incentive Program and will manage the payment of the LMM Payment to LMMs from the Exchange's general revenues. An LMM would not be entitled to an LMM Payment unless and until it meets or exceed the Incentive Program LMM Performance standards for an assigned ETP, as determined by the Exchange. The Exchange has represented that the Exchange will be responsible for assigning LMMs to particular ETPs, and an issuer's preference will not be determinative. Furthermore, the Optional Incentive Fees will be paid into the Exchange's general revenues, and the LMM Payments will be paid out of the Exchange's general revenues. If an LMM does not meet is Incentive Program LMM Performance Standards for an ETP for a given month, the issuer will not receive any refund or credit from the Exchange. If an issuer does not pay its quarterly installment of the Optional Incentive Fee for a particular ETP to the Exchange on time, the Exchange will continue to credit the LMM for LMM Payments as long as the LMM meets is Incentive Program LMM Performance Standards. The Commission believes that these factors, taken together, should help to mitigate the conflict of interest and other concerns that the Commission has previously identified [91] relating to issuers paying for market making.[92]

The Commission believes that it is reasonable and consistent with the Act for the Exchange to limit the Incentive Program to certain types of securities to allow the Exchange, through a pilot, to assess whether the program will have the desired effect of improving the market quality of these securities before implementing the program on a permanent basis. The Commission believes that it is reasonable and consistent with the Act for the Exchange to limit the Incentive Program to products under the 1,000,000 CADV threshold, to support the Exchange's stated purpose to ''support the provision

[85] FINRA has amended Rule 5250 to create an exception for payments to members that are expressly provided for under the rules of a national securities exchange that are effective after being filed with, or filed with and approved by, the Commission pursuant to the requirements of the Act. *See* Securities Exchange Act Release No. 69398 (Apr. 18, 2013), 78 FR 24261 (Apr. 24, 2013). This amendment to FINRA Rule 5250 became effective May 15, 2013.

[86] *See* Securities Exchange Act Release No. 38812 (July 3, 1997), 62 FR 37105 (July 10, 1997) (SR–NASD–97–29) (''NASD Rule 2460 Approval Order''), at 37107.

[87] *See id.* at 37107.

[88] *See id.*

[89] *See id.* at 37106.

[90] *See supra* Section I.

[91] *See* NASD Rule 2460 Approval Order, *supra* note 86, and *supra* notes 86–89. *See also* Securities Act Release No. 6334 (Aug. 6, 1981), 46 FR 42001 (Aug. 18, 1981), at Section IV.B (Treatment as Statutory Underwriter). The Exchange notes that the derivative and open-ended nature of many of the ETPs eligible to participate in the Incentive Program would allow for transparent intrinsic intraday pricing and, as such, the Exchange does not believe such products would lend themselves to the type of market manipulation that FINRA Rule 5250 was designed to prevent. *See* Notice, *supra* note 4, at 21688–9.

[92] Until the amendment to FINRA Rule 5250 to exempt payments made pursuant to the rules of a national securities exchange from the prohibition on payments by issuers to market makers under FINRA Rule 5250 becomes effective, receipt of payments pursuant to the Incentive Program by an LMM that is a FINRA member would be in violation of FINRA Rule 5250. *See supra* note 85.

of consistent liquidity in lower-volume ETPs listed on the Exchange.''[93]

The Commission believes that the Optional Incentive Fees are an equitable allocation of reasonable fees. First, participation in the Incentive Program is voluntary. An entity is free to determine whether it would be economically desirable to pay the Optional Incentive Fee, given the permitted range of the fee, the trading characteristics of the ETP, and the anticipated benefit. If an issuer chooses to participate in the Incentive Program with respect to an ETP, it will have the discretion to designate the amount of the Optional Incentive Fee it will pay, between $10,000 and $40,000. The Optional Incentive Fees will be paid for by either the issuer that has an ETP participating in the Incentive Program or the sponsor associated with such issuer. Thus, the Optional Incentive Fee will be incurred and paid for by an entity that has chosen to participate in, and that may potentially benefit from, the Incentive Program.[94] An entity that chooses not to participate will not be required to pay any additional fee beyond the standard listing and annual fees. Further, the permitted range of Optional Incentive Fees will be the same for any issuer wishing to participate in the program.

The Commission also believes that allowing the issuer some discretion when determining the amount of the Optional Incentive Fee amount is consistent with the Act. Not all ETPs are alike, and trading in certain products may be riskier or more costly than trading in others. The Commission believes that it is reasonable to allow each issuer to choose to participate in the program and to determine the amount, subject to a permitted range, at which it is desirable to incentivize LMMs through the Optional Incentive Fee to improve the market quality of ETPs participating in the program. Further, as discussed above, the payment of the Optional Incentive Fee will be transparent to the marketplace, as this information will be disclosed on the Exchange's Web site.

IV. Section 11(d)(1) of the Exchange Act

Section 11(d)(1) of the Exchange Act[95] generally prohibits a broker-dealer from extending or maintaining credit, or arranging for the extension or maintenance of credit, on shares of new issue securities, if the broker-dealer participated in the distribution of the new issue securities within the preceding 30 days. The Commission's view is that shares of open-end investment companies and unit investment trusts registered under the 1940 Act, such as ETP shares, are distributed in a continuous manner, and broker-dealers that sell such securities are therefore participating in the ''distribution'' of a new issue for purposes of Section 11(d)(1).[96]

The Division of Trading and Markets, acting under delegated authority, granted an exemption from Section 11(d)(1) and Rule 11d1–2 thereunder for broker-dealers that have entered into an agreement with an exchange-traded fund's distributor to place orders with the distributor to purchase or redeem the exchange-traded fund's shares (''Broker-Dealer APs).[97] The SIA Exemption allows a Broker-Dealer AP to extend or maintain credit, or arrange for the extension or maintenance of credit, to or for customers on the shares of qualifying exchange-traded funds subject to the condition that neither the Broker-Dealer AP, nor any natural person associated with the Broker-Dealer AP, directly or indirectly (including through any affiliate of the Broker-Dealer AP), receives from the fund complex any payment, compensation, or other economic incentive to promote or sell the shares of the exchange-traded fund to persons outside the fund complex, other than non-cash compensation permitted under NASD Rule 2830(l)(5)(A), (B), or (C). This condition is intended to eliminate special incentives that Broker-Dealer APs and their associated persons might otherwise have to ''push'' exchange-traded fund shares.[98]

The Incentive Program will permit certain ETPs to voluntarily incur increased listing fees payable to the Exchange. In turn, the Exchange will use the fees to make incentive payments to market makers that improve the liquidity of participating issuers' securities, and thus enhance the market quality for the participating issuers. Incentives payments will be accrued for, among other things, executing purchases and sales on the Exchange. Receipt of the incentive payments by certain broker-dealers will implicate the conditions of the SIA Exemption[99] from the new issue lending restriction in Section 11(d)(1) of the Exchange Act discussed above. The Commission's view is that the incentive payments market makers will receive under the proposal are indirect payments from the fund complex to the market maker and that those payments are compensation to promote or sell the shares of the ETP. Therefore, a market maker that is also a broker-dealer receiving the incentives will not be able to rely on the SIA Exemption from Section 11(d)(1).[100] This does not mean that broker-dealers cannot participate in the Incentive Program; it merely means they cannot rely on the SIA Exemption[101] while

[93] *See* Notice, *supra* note 4, at 21688. In addition, under the proposal an issuer would not be permitted to have more than five existing ETPs (*i.e.,* ETPs that are listed on the Exchange prior to the pilot) participate in the Incentive Program. The Commission believes that it is reasonable and consistent with the Act for the Exchange to limit the number of existing ETPs per issuer that may participate in the Incentive Program during the pilot period, as all issuers participating in the program will be subject to this limit. Furthermore, such limit should allow for the analysis of the impact of the Fixed Incentive Program during the pilot on eligible ETPs participating and not participating in the program, as the number of those existing eligible ETPs that may participate in the program will be limited.

[94] Issuers of exchange-traded funds registered under the 1940 Act are prohibited from paying directly or indirectly for distribution of their shares (*i.e.,* directly or indirectly financing any activity that is primarily intended to result in the sale of shares), unless such payments are made pursuant to a plan that meets the requirements of Rule 12b–1 under the 1940 Act. Although the services at issue could be primarily intended to result in the sale of fund shares, the Commission has stated that such a determination will depend on the surrounding circumstances. *See Payment of Asset-Based Sales Loads by Registered Open-End Management Investment Companies,* Investment Company Act Release No. 16431 (June 13, 1988) (''1988 12b–1 Release''). As the Commission has noted previously, if a fund makes payments that are ostensibly for a non-distribution purpose, and the recipient of those payments finances distribution, the question arises whether the fund's assets are being used indirectly for distribution. The Commission has stated that there can be no precise definition of what types of expenditures constitute indirect use of fund assets, and this determination is based on the facts and circumstances of each individual case. In addition, fund directors, particularly independent directors bear substantial responsibility for making that judgment. *See Bearing of Distribution Expenses by Mutual Funds,* Investment Company Act Release No. 11414 (October 28, 1980).

[95] 15 U.S.C. 78k(d)(1).

[96] *See, e.g.,* Exchange Act Release Nos. 6726 (Feb. 8, 1962), 27 FR 1415 (Feb. 15, 1962) and 21577 (Dec. 18, 1984), 49 FR 50174 (Dec. 27, 1984).

[97] *See* Letter from Catherine McGuire, Chief Counsel, Division of Trading and Markets, Securities and Exchange Commission to Securities Industry Association (Nov. 21, 2005) (''SIA Exemption'').

[98] Trading and markets staff provided no-action relief from Section 11(d)(1) for broker-dealers engaging in secondary market proprietary or customer transactions in securities of Commodity-based Exchange-Traded Trusts (''CBETTs'') similar to the Commission's SIA Exemption. This relief is conditioned on the broker-dealer and any natural person associated with the broker-dealer not receiving from the Fund complex, directly or indirectly, any payment, compensation or other economic incentive to promote or sell Shares to persons outside of the Fund complex, other than non-cash compensation permitted under NASD Rule 2830(1)(5)(A), (B), or (C). *See* No-Action Letter re: DB Commodity Index Tracking Fund and DB Commodity Services LLC (Jan. 19, 2006); No-Action Letter re: Rydex Specialized Products LLC (Dec. 5, 2005); No-Action Letter re: streetTRACKS Gold Trust (Dec. 12, 2005); and No-Action Letter re: iShares COMEX Gold Trust (Dec. 12, 2005).

[99] *See also* note 98, *supra.*

[100] *Id.*

[101] *Id.*

doing so. Thus, broker-dealers that participate in the Incentive Program will need to comply with Section 11(d)(1) unless there is another applicable exemption.

V. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,[102] that the proposed rule change (SR–NYSEArca-2013–34), as modified by Amendment Nos. 1 and 2 thereto, be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[103]

Kevin M. O'Neill,

Deputy Secretary.

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[102] 15 U.S.C. 78s(b)(2).

[103] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–69710; File No. SR–MIAX–2013–26]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the MIAX Fee Schedule

June 6, 2013.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1], and Rule 19b–4 thereunder,[2] notice is hereby given that on May 30, 2013, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend its Fee Schedule.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing*, at MIAX's principal office, and at the Commission's Public Reference Room.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to waive all transaction fees in Section 1(a)(i) of the MIAX Options Fee Schedule that apply to Market Makers [3] registered on the Exchange for the period beginning June 3, 2013 and ending July 31, 2013.[4] Specifically, during this period, the Exchange will waive the following transaction fees: (i) RMMs $0.23 per contract for standard options or $0.023 for Mini Options; (ii) LMMs $0.20 per contract for standard options or $0.020 for Mini Options; (iii) DLMMs and PLMMs $0.18 per contract for standard options or $0.018 for Mini Options; and (iv) DPLMMs $0.16 per contract for standard options or $0.016 for Mini Options.[5]

The proposed fee waiver is designed to both enhance the Exchange's competitiveness with other option exchanges and strengthen its market quality. The Exchange believes that the proposed change would increase both intermarket and intramarket competition by incenting market participants and market makers on other exchanges to register as Market Makers on the Exchange. In addition, the Exchange believes that waiving transaction fees for Market Makers registered on the Exchange will promote tighter bid-ask spreads by Market Makers, and increase the volume of transactions in order to allow the Exchange to compete more effectively with other options exchanges for such transactions.

The Exchange notes that, while the proposal is not based on that of another exchange, that fee waivers are often used by exchanges to increase their competitiveness.[6]

The proposed rule change will take effect on June 3, 2013.

Technical Change

In addition to the changes above, the Exchange proposes a technical change to the Fee Schedule to delete an obsolete date. Specifically, the Exchange proposes to delete the language ''Effective April 17, 2013'' from the heading in Section 1 of the Fee Schedule. The Exchange believes that including this date in the Fee Schedule in this location is unnecessary going forward.

2. Statutory Basis

The Exchange believes that its proposal to amend its fee schedule is consistent with Section 6(b) of the Act [7] in general, and furthers the objectives of Section 6(b)(4) of the Act [8] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange believes that the proposed fee waiver is fair, equitable and not unreasonably discriminatory. The proposed fee waiver is reasonable because it waives transaction fees for a limited period in order to enable the Exchange to improve its overall competitiveness and strengthen its market quality for all market participants. The proposed fee waiver is fair and equitable and not unreasonably discriminatory because it will apply equally to all Market Makers. All similarly situated Market Makers are subject to the same fee waiver, and access to the Exchange is offered on

[3] Market Makers may be registered as a Lead Market Maker or as a Registered Market Maker. *See* Exchange Rule 600(b). Market Makers registered on the Exchange for purposes of the transaction fee waiver and Section 1(a)(i) of the Fee Schedule include: (i) Registered Market Maker (''RMM''); (ii) Lead Market Maker (''LMM''); (iii) Directed Order Lead Market Maker (''DLMM''); (iv) Primary Lead Market Maker (''PLMM''); and Directed Order Primary Lead Market Maker (''DPLMM''). *See* MIAX Options Fee Schedule, Section 1(a)(i)—Market Maker Transaction Fees.

[4] The fee waiver will only apply to Market Maker transaction fees in Section 1(a)(i) of the MIAX Options Fee Schedule. *See* MIAX Options Fee Schedule, Section 1(a)(i)—Market Maker Transaction Fees. The Exchange notes that the proposal will have no effect on other fees and dues that may apply to Market Makers including marketing fees, Options Regulatory Fees, market data, and membership application fees. At the end of the period, Market Maker Transaction Fees will return to the prior fee rates unless the Exchange files another 19b–4 Rule Filing to amend its fees.

[5] *See* MIAX Options Fee Schedule, Section 1(a)(i)—Market Maker Transaction Fees.

[6] *See e.g.,* Securities Exchange Act Release Nos. 66427 (February 21, 2012), 77 FR 11608 (February 27, 2012) (SR–BATS–2012–011); 65007 (August 2, 2011), 76 FR 48190 (August 8, 2011) (SR–CBOE–2011–071); 56862 (November 29, 2007), 72 FR 68918 (December 6, 2007) (SR–CBOE–2007–135); 55833 (May 31, 2007), 72 FR 31358 (June 6, 2007) (SR–ISE–2007–28).

[7] 15 U.S.C. 78f(b).

[8] 15 U.S.C. 78f(b)(4).

terms that are not unfairly discriminatory. The registration as an Exchange Market Maker is equally available to all market participants and Electronic Exchange Members (''EEMs'') that satisfy the requirements of Rule 600. Any market participant may choose to satisfy the additional requirements and obligations of being a Market Maker in order to qualify for the transaction fee waiver.

The proposal to waive the transaction fees for Market Makers, and no other market participants, is equitable and not unfairly discriminatory because Market Markers on the Exchange have enhanced quoting obligations measured in both quantity (% time) and quality (minimum bid-ask differentials) that other market participants do not have.[9] The proposal is reasonably designed to enhance the quality of quoting and volume transactions by limiting the proposal to those market participants that have these enhanced obligations to deliver quality markets. Waiving fees during this period should incent market participants and market makers on other exchanges to register as Market Makers on the Exchange, which will enhance the quality of quoting and increase the volume of contracts traded here. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity. Enhanced market quality and increased transaction volume that results from the anticipated increase in Market Maker activity on the Exchange will benefit all market participants and improve competition on the Exchange.

The Exchange believes that an increase in the number of Market Makers, and an increase in the execution volume from Market Makers, will result in increased revenue from other fees and dues that may apply to Market Makers that may potentially offset a portion of the fee waiver.[10] While the Exchange believes that an increase in the number of Market Makers, and an increase in the execution volume from Market Makers, may potentially result in increased trading activity of other market participants, the Exchange does not believe that the fee waiver will result in other market participants subsidizing the activity of Market Makers during the fee waiver period since the Exchange is not proposing any changes to increase the existing fees of other market participants in order to compensate for the temporary transaction fee waiver.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that proposed change would increase both intermarket and intramarket competition by incenting market participants and market makers on other exchanges to register as Market Makers on the Exchange, which will enhance the quality of quoting and increase the volume of contracts traded here. To the extent that there is addition [sic] competitive burden on non-Market Makers, the Exchange believes that this is appropriate because Market Markers registered on the Exchange have enhanced quoting obligations measured in both quantity (% time) and quality (minimum bid-ask differentials) that other market participants do not have. Waiving fees during this period should incent market participants and market makers on other exchanges to register as Market Makers on the Exchange, which will enhance the quality of quoting and increase the volume of contracts traded here. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity. Enhanced market quality and increased transaction volume that results from the anticipated increase in Market Maker activity on the Exchange will benefit all market participants and improve competition on the Exchange. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow. The Exchange believes that the proposed rule change reflects this competitive environment because it reduces the Exchange's fees in a manner that encourages market participants to register as Market Makers, to provide liquidity, and to attract order flow to the Exchange. Given the robust competition for volume among options markets, many of which offer the same products, implementing a fee waiver program to attract Market Maker volume like the one being proposed in this filing is consistent with the above-mentioned goals of the Act. This is especially true for the smaller options markets, such as MIAX, which is competing for volume with much larger exchanges that dominate the options trading industry. As a new exchange, MIAX has a nominal percentage of the average daily trading volume in options, so it is unlikely that the fee waiver could cause any competitive harm to the options market or to market participants. Rather, the fee waiver is a modest attempt by a small options market to attract order volume away from larger competitors by adopting an innovative pricing strategy. The Exchange notes that if the fee waiver resulted in a modest percentage increase in the average daily trading volume in options executing on MIAX, while such percentage would represent a large volume increase for MIAX, it would represent a minimal reduction in volume of its larger competitors in the industry. The Exchange believes that the proposal will help further competition, because market participants will have yet another additional option in determining where to execute orders and post liquidity if they factor the benefits of Market Maker transaction fees into the determination.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act.[11] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

[9] *See* MIAX Rules 603, 604, 605.

[10] The Exchange notes that the proposal will have no effect on other fees and dues that may apply to Market Makers including marketing fees, Options Regulatory Fees, market data, and membership application fees.

[11] 15 U.S.C. 78s(b)(3)(A)(ii).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–MIAX–2013–26 on the subject line.

Paper Comments

- Send paper comments in triplicate to Elizabeth M. Murphy, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–MIAX–2013–26. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–MIAX–2013–26 and should be submitted on or before July 3, 2013.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Kevin M. O'Neill,

Deputy Secretary.

[FR Doc. 2013–13897 Filed 6–11–13; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

Polar Petroleum Corp.; Order of Suspension of Trading

June 10, 2013.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Polar Petroleum Corp. (''Polar'') because of questions regarding the adequacy and accuracy of assertions by Polar, and by others, to investors in press releases and promotional material concerning, among other things, the company's assets, operations, and financial condition. Polar is a Nevada corporation based in Anchorage, Alaska; it is dually quoted on the OTCBB and OTC Link under the symbol POLR.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT on June 10, 2013 through 11:59 p.m. EDT on June 21, 2013.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2013–14027 Filed 6–10–13; 11:15 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice 8352]

Persons on Whom Sanctions Have Been Imposed Pursuant to the Iran Sanctions Act of 1996, as Amended, and Executive Order 13622

AGENCY: Department of State.

ACTION: Notice.

SUMMARY: The Secretary of State has determined, pursuant to authority delegated by the (the ''Delegation Memorandum'')(see 77 FR 62139, October 12, 2012), that the following person has engaged in sanctionable activity described in section 5(a)(8) of the Iran Sanctions Act of 1996 (Pub. L. 104–172) (50 U.S.C. 1701 note) (''ISA''), as amended, and that certain sanctions are imposed as a result: Ferland Company Limited.

The Secretary of State also has determined that the following persons have engaged in sanctionable activity described in section 2(a)(ii) of Executive Order 13622—Authorizing Additional Sanctions With Respect to Iran, and that certain sanctions are imposed as a result: Jam Petrochemical Company and Niksima Food and Beverage JLT.

DATES: *Effective Date:* The sanctions on Ferland Company Limited, Jam Petrochemical Company, and Niksima Food and Beverage JLT are effective May 31, 2013.

FOR FURTHER INFORMATION CONTACT: On general issues: Office of Sanctions Policy and Implementation, Department of State, Telephone: (202) 647–7489.

SUPPLEMENTARY INFORMATION: Pursuant to section 5(a)(8) of the ISA and the Delegation Memorandum, the Secretary determined that the following sanctions as described in section 6 of the ISA are to be imposed on Ferland Company Limited:

1. Banking transactions. Any transfers of credit or payments between financial institutions or by, through, or to any financial institution, to the extent that such transfers or payments are subject to the jurisdiction of the United States and involve any interest of Ferland Company Limited, shall be prohibited.

2. Property transactions. It shall be prohibited to:

a. Acquire, hold, withhold, use, transfer, withdraw, transport, import, or export any property that is subject to the jurisdiction of the United States and with respect to which Ferland Company Limited has any interest;

b. Deal in or exercise any right, power, or privilege with respect to such property; or

c. Conduct any transactions involving such property.

3. Foreign Exchange. Any transactions in foreign exchange that are subject to the jurisdiction of the United States and which involve any interest of Ferland Company Limited shall be prohibited.

4. Loans from United States Financial Institutions. Loans or provision of credits to Ferland Company Limited totaling more than $10,000,000 over a 12-month period from any United States Financial Institution shall be prohibited.

5. Exclusion of corporate officers. The Secretary of State shall deny a visa to, and the Secretary of Homeland Security shall exclude from the United States, the following corporate officers of Ferland Company Limited:

a. Vitaly Sokolenko.

Pursuant to Executive Order (E.O.) 13622, the Secretary determined that the following sanctions as described in section 4 of E.O. 13622 are to be imposed on Jam Petrochemical Company:

1. Banking transactions. Any transfers of credit or payments between financial

institutions or by, through, or to any financial institution, to the extent that such transfers or payments are subject to the jurisdiction of the United States and involve any interest of Jam Petrochemical Company, shall be prohibited.

2. Blocking all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person, including any foreign branch, of Jam Petrochemical Company, and providing that such property and interests in property may not be transferred, paid, exported, withdrawn or otherwise dealt in.

3. Foreign Exchange. Any transactions in foreign exchange that are subject to the jurisdiction of the United States and which involve any interest of Jam Petrochemical Company, shall be prohibited.

Pursuant to Executive Order (E.O.) 13622, the Secretary determined that the following sanctions as described in section 4 of E.O. 13622 are to be imposed on Niksima Food and Beverage JLT:

1. Banking transactions. Any transfers of credit or payments between financial institutions or by, through, or to any financial institution, to the extent that such transfers or payments are subject to the jurisdiction of the United States and involve any interest of Niksima Food and Beverage JLT, shall be prohibited.

2. Blocking all property and interests in property that are in the United States, that come within the United States, or that are or come within the possession or control of any United States person, including any foreign branch, of Jam Petrochemical Company, and providing that such property and interests in property may not be transferred, paid, exported, withdrawn or otherwise dealt in.

3. Foreign Exchange. Any transactions in foreign exchange that are subject to the jurisdiction of the United States and which involve any interest of Niksima Food and Beverage JLT, shall be prohibited.

The sanctions described above with respect to Ferland Company Limited, Jam Petrochemical Company, and Niksima Food and Beverage JLT shall remain in effect until otherwise directed pursuant to the provisions of the ISA or other applicable authority. Pursuant to the authority delegated to the Secretary of State in the Delegation Memorandum and consistent with any relevant Executive Orders, relevant agencies and instrumentalities of the United States Government shall take all appropriate measures within their authority to carry out the provisions of this notice. The Secretary of the Treasury is taking appropriate action to implement the sanctions for which authority has been delegated to the Secretary of the Treasury pursuant to the Delegation Memorandum, Executive Order 13622 of July 30, 2012, and Executive Order 13628 of October 9, 2012.

The following constitutes a current list, as of this date, of persons on whom ISA sanctions have been imposed. The particular sanctions imposed on an individual person are identified in the relevant **Federal Register** Notice.

—Associated Shipbroking (a.k.a. SAM) (see Public Notice 7585, 76 FR 56866, September 14, 2011)
—Belarusneft (see Public Notice 7408, 76 FR 18821, April 5, 2011)
—Bimeh Markazi-Central Insurance of Iran (see Public Notice 8268, 76 Fed. Reg. 21183, April 9, 2013)
—Cambis, Dimitris (see Public Notice 8268, 76 Fed. Reg. 21183, April 9, 2013)
—FAL Oil Company Limited (see Public Notice 7776, 77 FR 4389, Jan. 27, 2012)
—Ferland Company Limited
—Impire Shipping (see Public Notice 8268, 76 Fed. Reg. 21183, April 9, 2013)
—Kish Protection and Indemnity (a.k.a. Kish P&I) (see Public Notice 8268, 76 Fed. Reg. 21183, April 9, 2013)
—Kuo Oil (S) Pte. Ltd. (see Public Notice 7776, 77 FR 4389, Jan. 27, 2012)
—Naftiran Intertrade Company (see Public Notice 7197, 75 FR 62916, Oct. 13, 2010)
—Petrochemical Commercial Company International (a.k.a. PCCI) (see Public Notice 7585, 76 FR 56866, September 14, 2011)
—Petro´leos de Venezuela S.A. (see Public Notice 7585, 76 FR 56866, September 14, 2011)
—Royal Oyster Group (see Public Notice 7585, 76 FR 56866, September 14, 2011)
—Speedy Ship (a.k.a. SPD) (see Public Notice 7585, 76 FR 56866, September 14, 2011)
—Sytrol (see Public Notice 8040, 77 FR 59034, September 18, 2012)
—Zhuhai Zhenrong Company (see Public Notice 7776, 77 FR 4389, Jan. 27, 2012)

Dated: June 5, 2013.

Jose W. Fernandez,

Assistant Secretary of State for Economic and Business Affairs.

[FR Doc. 2013–13968 Filed 6–11–13; 8:45 am]

BILLING CODE 4710–07–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits

Notice of Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits Filed Under Subpart B (formerly Subpart Q) during the Week Ending May 25, 2013. The following Applications for Certificates of Public Convenience and Necessity and Foreign Air Carrier Permits were filed under Subpart B (formerly Subpart Q) of the Department of Transportation's Procedural Regulations (See 14 CFR 301.201 et. seq.). The due date for Answers, Conforming Applications, or Motions to Modify Scope are set forth below for each application. Following the Answer period DOT may process the application by expedited procedures. Such procedures may consist of the adoption of a show-cause order, a tentative order, or in appropriate cases a final order without further proceedings.

Docket Number: DOT- OST–2013–0109.

Date Filed: May 21, 2013.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: June 11, 2013.

Description: Application of AirTanker Services Limited requesting a foreign air carrier permit and exemption authority to engage in: (a) Foreign charter air transportation of persons and property from any point or points behind any Member State of the European Union via any point or points in any Member State and via intermediate points to any point or points in the United States and beyond; (b) foreign charter air transportation of persons and property between any point or points in the United States and any point or points in any member of the European Common Aviation Area; (c) other charters pursuant to the prior approval requirements set forth in Part 212 of the Department's Economic Regulations; and (d) transportation authorized by any additional route rights made available to European Community carries in the future.

Barbara J. Hairston,

Acting Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2013–13961 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending May 25, 2013

The following Agreements were filed with the Department of Transportation under the Sections 412 and 414 of the Federal Aviation Act, as amended (49 U.S.C. 1382 and 1384) and procedures governing proceedings to enforce these provisions. Answers may be filed within

21 days after the filing of the application.

Docket Number: DOT–OST–2013–0110.

Date Filed: May 24, 2013.

Parties: Members of the International Air Transport Association.

Subject:

PTC COMP Mail Vote 734.

Resolution 024d Currency Names, Codes.

Rounding Units and Acceptability of Currencies.

South Africa Implementation date: 17 June 2013

(Memo PTC COMP 1713).

Intended effective date: June 10, 2013.

Barbara J. Hairston,

Acting Program Manager, Docket Operations, Federal Register Liaison.

[FR Doc. 2013–13962 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–9X–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. PE–2013–18]

Petition for Exemption; Summary of Petition Received

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition for exemption received.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of 14 CFR. The purpose of this notice is to improve the public's awareness of, and participation in, this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before July 2, 2013.

ADDRESSES: You may send comments identified by Docket Number FAA–2013–0355 using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Send comments to the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue, SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.
- *Fax:* Fax comments to the Docket Management Facility at 202–493–2251.
- *Hand Delivery:* Bring comments to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to the Docket Management Facility in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Keira Jones (202) 267–4024, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC, on June 7, 2013.

Ida M. Klepper,

Acting Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2013–0355.

Petitioner: ExpressJet Airlines, Inc.

Section of 14 CFR Affected: 14 CFR 61.159(a).

Description of Relief Sought: Express Jet seeks limited relief to permit its pilots to credit training in a simulator in an approved course of training under part 121 to count toward the aeronautical experience requirements for an airline transport pilot certificate.

[FR Doc. 2013–13898 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

[Docket No. FHWA–2013–0034]

Agency Information Collection Activities: Request for Comments for a New Information Collection

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Notice and request for comments.

SUMMARY: FHWA invites public comments about our intention to request the Office of Management and Budget's (OMB) approval for a new information collection, which is summarized below under **SUPPLEMENTARY INFORMATION**. We published a **Federal Register** Notice with a 60-day public comment period on this information collection on March 5, 2013. We are required to publish this notice in the **Federal Register** by the Paperwork Reduction Act of 1995.

DATES: Please submit comments by July 12, 2013.

ADDRESSES: You may send comments within 30 days to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention DOT Desk Officer. You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burden; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. All comments should include the Docket number FHWA–2013–0034.

FOR FURTHER INFORMATION CONTACT: Mark Ferroni, 202–366–3233, Office of Planning, Environment, and Realty, Federal Highway Administration, Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590. Office hours are from 6:00 a.m. to 3:30 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Title: Noise Barrier Inventory.

Background: The basis of the Federal-aid highway program is a strong federal-state partnership. At the core of that partnership is a philosophy of trust and flexibility, and a belief that the states are in the best position to make investment decisions and that states base these decisions on the needs and priorities of their citizens. The FHWA noise regulation (23 CFR Part 772) gives each state department of transportation (SDOT) flexibility to determine the feasibility and reasonableness of noise abatement by balancing of the benefits of noise abatement against the overall adverse social, economic, and environmental effects and costs of the noise abatement measures. The SDOT must base its determination on the interest of the overall public good,

keeping in mind all the elements of the highway program (need, funding, environmental impacts, public involvement, etc.).

Reduction of highway traffic noise should occur through a program of shared responsibility with the most effective strategy being implementation of noise compatible planning and land use control strategies by state and local governments. Local governments can use their power to regulate land development to prohibit noise-sensitive land use development adjacent to a highway, or to require that developers plan, design, and construct development in ways that minimize noise impacts. The FHWA noise regulations limit Federal participation in the construction of noise barriers along existing highways to those projects proposed along lands where land development or substantial construction predated the existence of any highway.

The data reflects the flexibility in noise abatement decision-making. Some states have built many noise barriers while a few have built none. Through the end of 2010, 47 SDOTs and the Commonwealth of Puerto Rico have constructed over 2,748 linear miles of barriers at a cost of over $4.05 billion ($5.44 billion in 2010 dollars). Three states and the District of Columbia have not constructed noise barriers. Ten SDOTs account for approximately sixty-two percent (62%) of total barrier length and sixty-nine percent (69%) of total barrier cost. The type of information requested can be found in 23CFR772.13(f).

The previously distributed listing can be found at *http://www.fhwa.dot.gov/environment/noise/noise_barriers/inventory/summary/sintro7.cfm*. This listing continues to be extremely useful in the management of the highway traffic noise program, in our technical assistance efforts for State highway agencies, and in responding to inquiries from congressional sources, Federal, State, and local agencies, and the general public. An updated listing of noise barriers will be distributed nationally for use in the highway traffic noise program. It is anticipated that this information will be requested in 2014 (for noise barriers constructed in 2011, 2012 and 2013) and then again in 2017 (for noise barriers constructed in 2014, 2015 and 2016). After review of the ''Summary of Noise Barriers Constructed by December 31, 2004'' document, a SDOT may request to delete, modify or add information to any calendar year.

Respondents: Each of the 50 SDOTs, the District of Columbia, and the Commonwealth of Puerto Rico.

Frequency: Every 3 years.

Estimated Average Burden per Response: It is estimated that on average it would take 8 hours to respond to this request.

Estimated Total Annual Burden Hours: It is estimated that the estimated total annual burden is 139 hours.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including: (1) Whether the proposed collection is necessary for the FHWA's performance; (2) the accuracy of the estimated burdens; (3) ways for the FHWA to enhance the quality, usefulness, and clarity of the collected information; and (4) ways that the burden could be minimized, including the use of electronic technology, without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1.48.

Issued On: June 7, 2013.

Michael Howell,

Information Collection Officer.

[FR Doc. 2013–13973 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–22–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2012–0024; Notice 2]

Supreme Indiana Operations, Inc., Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Grant of Petition.

SUMMARY: Startrans, a division of Supreme Indiana Operations, Inc., (Startrans)[1] has determined that certain Startrans trucks, buses, and multifunction school activity buses (MFSAB) manufactured from 2006 through 2011, do not fully comply with paragraph § 5.3 of Federal Motor Vehicle Safety Standard (FMVSS) No. 120, *Tire selection and rims and motor home/recreation vehicle trailer load carrying capacity information for motor vehicles with a GVWR of more than 4,536 kilograms (10,000 pounds).* Startrans has filed an appropriate report pursuant to 49 CFR Part 573, *Defect and Noncompliance Responsibility and Reports,* dated November 16, 2011.

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR Part 556, Startrans has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety.

Notice of receipt of Startran's petition was published, with a 30-day public comment period, on March 22, 2012, in the **Federal Register** (77 FR 16893). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2012–0024.''

Contact Information: For further information on this decision, contact Ms. Amina Fisher, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–1018.

Vehicles Invovled: Affected are approximately 436 MFSAB (Activity School Buses) manufactured between 2007 and 2011, 9,543 School Buses manufactured between 2007 and 2011, 97,271 Truck models manufactured between 2006 and 2011, for a total of approximately 107,250 vehicles not in compliance with FMVSS No. 120.

Summary of Startrans' Analysis and Arguments: Startrans explains that the noncompliance is that the height of the lettering on the combined certification and tire information labels attached to the subject vehicles is less than that required by paragraph § 5.3 of FMVSS No. 120. The lettering on the noncompliant labels is only 2.12 millimeters (mm) in height. The height required by paragraph § 5.3 is 2.4 mm.

Startrans determined that the subject noncompliance existed after being notified by the NHTSA's Office of Vehicle Safety Compliance (OVSC) that an apparent noncompliance was identified during an OVSC FMVSS No. 120 compliance test of a model year 2010 Startrans MFSAB.

Startrans makes the argument that the subject noncompliance is not performance related and is inconsequential to vehicle safety. The font height of the text on the certification label is just 0.28 mm less than the requirement, but the label text is clear, legible and meets all the other labeling requirements.

[1] Supreme Indiana Operations, Inc., is manufacturer of motor vehicles and is registered under the laws of the state of Delaware.

Startrans also states that the number of vehicles that potentially require remedy is 107,250 and represents several concerns. These vehicles are already registered and currently represent no concern with licensing. To perform a remedy on this many vehicles invites the possibility of certification decals being reinstalled on the wrong vehicles.

Startrans has additionally informed NHTSA that it has corrected the noncompliance so that all future production vehicles will comply with FMVSS No. 120.

In summation, Startrans believes that the described noncompliance of its vehicles is inconsequential to motor vehicle safety, and that its petition, to exempt from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

Background Requirement: Section § 5.3 of FMVSS No. 120 specifically states:

§ 5.3 Each vehicle shall show the information specified in § 5.3.1 and § 5.3.2 and, in the case of a vehicle equipped with a non-pneumatic spare tire, the information specified in § 5.3.3, in the English language, lettered in block capitals and numerals not less than 2.4 millimeters high and in the format set forth following this paragraph. This information shall appear either—

(a) After each GAWR listed on the certification label required by § 567.4 or § 567.5 of this chapter; or at the option of the manufacturer,

(b) On the tire information label affixed to the vehicle in the manner, location, and form described in § 567.4 (b) through (f) of this chapter as appropriate of each GVWR–GAWR combination listed on the certification label.

NHTSA Decision: NHTSA has reviewed and accepts Startrans analyses that the noncompliance is inconsequential to motor vehicle safety. In addition, NHTSA has verified that the certification and tire labels do comply with all other safety performance requirements of FMVSS No. 120. NHTSA agrees that, despite the lettering size discrepancy, the labels are clear and legible.

In consideration of the foregoing, NHTSA has determined that Startrans has met its burden of persuasion that the subject FMVSS No. 120 labeling noncompliance is inconsequential to motor vehicle safety. Accordingly, Startrans' petition is hereby granted, and Startrans is exempted from the obligation of providing notification of, and remedy for, the subject noncompliance under 49 U.S.C. 3018 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to approximately 107,250 vehicles that Startrans no longer controlled at the time that it determined that a noncompliance existed in the subject vehicles. However, the granting of this petition does not relieve vehicle distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant vehicles under their control after Startrans notified them that the subject noncompliance existed.

Authority: (49 U.S.C. 30118, 30120: delegations of authority at CFR 1.95 and 501.8)

Issued On: June 5, 2013.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–13920 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2012–0006; Notice 2]

General Motors, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Grant of Petition.

SUMMARY: General Motors, LLC (GM), has determined that certain model year 2012; Cadillac SRX, Chevrolet Equinox, GMC Terrain and Saab 9–4x multipurpose passenger vehicles, and Chevrolet Cruze passenger cars, do not fully comply with paragraph § 19.2.2 of Federal Motor Vehicle Safety Standard (FMVSS) No. 208, *Occupant Crash Protection.* GM has filed an appropriate report pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports,* dated September 6, 2011.

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, GM has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety. Notice of receipt of GM's petition was published, with a 30-day public comment period, on August 9, 2012, in the **Federal Register** (77 FR 47697). No comments were received. To view the petition, the comments, and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2012–0006.''

For further information on this decision, contact Mr. Charles Case, Office of Vehicle Safety Compliance, NHTSA, telephone (202) 366–5319.

Vehicles Involved: Affected are approximately 3,599 Cadillac SRX, 11,459 Chevrolet Equinox, 5,080 GMC Terrain and 24 Saab 9–4x multipurpose passenger vehicles; and 27,392 Chevrolet Cruze passenger cars, a total of approximately 47,554 vehicles not in compliance with FMVSS No. 208. All of the vehicles are model year 2012 and were manufactured within the period from April 6, 2011 through August 20, 2011.

Summary of GM's Analysis and Arguments: GM explained that the noncompliance is that on rare occasions, the front passenger air bag suppression status telltale lamp on the subject vehicles may remain illuminated during a particular ignition cycle and indicate that the passenger air bag is OFF regardless of whether the air bag is or is not suppressed.

GM further explains that for this noncompliance condition to exist, the following must occur:

(1) The engine must be restarted within approximately 24 seconds of having been turned OFF;

(2) The key [1] must be turned rapidly, spending less than 10 milliseconds (0.01 seconds) in the RUN position before it reaches the START position; and

(3) The crank power mode (approximately how long the starter motor runs) must be less than 1.2 seconds. GM's data predicts that the conditions for a noncompliance to occur will happen, on average, approximately once every 18 months, independent of whether the front seat is occupied or not.

GM stated its belief that this noncompliance is inconsequential to motor vehicle safety for the following reasons:

A. The noncompliance does not increase the risk to motor vehicle safety because it has no effect on occupant

[1] Cadillac SRX and Saab 9–4X vehicles have a push button start/stop switch.

restraint. The noncompliant condition has absolutely no effect on the proper operation of the occupant classification system. If the telltale error occurs when an occupant or a Child Restraint System (CRS) is in the front passenger seat, the occupant classification system will operate as designed, and will enable or disable the air bag, as intended, and continue to meet the requirements of FMVSS No. 208 in all other regards. As a result, all occupants will continue to receive the benefit of the air bag when they otherwise would, regardless of whether or not the telltale is operating properly during a particular ignition cycle.

B. The noncompliance condition is an extremely remote event. The noncompliance condition will not occur unless the engine is shut off and restarted within about 24 seconds. Even then, the condition will not occur unless the ignition key spends less than a hundredth of a second in the RUN position before reaching the START position, and the crank power mode lasts less than 1.2 seconds. These are very prescribed, unusual conditions. GM discovered the condition during an assembly plant end of line audit when it was noted that the telltale illuminated OFF when an adult passenger was present. GM is not aware of any reports in the field about the condition.

When this condition occurs, it sets a Diagnostic Trouble Code (DTC) that is stored in history in the sensing diagnostic module for 100 ignition cycles. GM reviewed its test fleet experience for the subject vehicles, and determined that the conditions needed to produce the telltale error will occur on average once every 535 days, or approximately, once every 18 months regardless of whether the front passenger seat is occupied or not.

C. Even if the air bag was enabled when the telltale indicated it was disabled, that would be extremely unlikely to increase the risk to motor vehicle safety. A potential safety risk could exist if the telltale indicated the air bag was OFF when the air bag was actually ON and a small child or CRS was placed in the front passenger seat. As explained in more detail below, this is extremely unlikely to occur in the present case. Parents and caregivers are warned to properly restrain small children and CRSs in the rear seat, and field data shows small children and CRSs are generally not placed in the front seat. In addition, GM has conducted significant testing to help assure that the air bag suppression system will properly disable the air bag system for small children and CRSs, as designed.

1. Children and CRSs generally are not placed in the front seat. It is very unlikely that a small child or a CRS would be placed in the front seat since parents and caregivers are routinely advised by NHTSA, pediatricians, child safety advocacy groups, and public service messages to properly restrain them in the rear seat. As NHTSA states in its Child Safety Recommendations for All Ages, ''All children under 13 should ride in the back seat.''

In addition, the label on the vehicle's sun visor warns against placing a rear facing infant seat in the front passenger seat, and the owner's manual warns against placing children in the front seat, as well, even for vehicles equipped with a passenger sensing system.

Publicly available data confirms that parents and caregivers generally do not place small children in the front passenger seat. According to GM's calculations using National Accident Sampling System (NASS) data, six month old, three year old and six year old children collectively are likely to occupy the front passenger seat during less than one half of one percent of all trips. This fact, together with the infrequency with which the noncompliance condition occurs, makes it extremely unlikely that a child or CRS would be placed in the front seat when the conditions needed to produce the telltale error occur.

2. Even if a small child or CRS was in the front seat. GM has conducted extensive testing to help assure that the air bag suppression system will properly characterize these occupants, so that the air bag will be suppressed, as designed. GM has had significant field experience with suppression systems of the type used in the subject vehicles. GM has used pattern recognition based suppression systems since 2005 and capacitance based suppression systems since 2009.

GM has conducted over 15,000 tests of the suppression systems in the subject vehicles, based on FMVSS 208 as well as GM's own internal requirements, to judge performance for properly positioned as well as out of position occupants and CRSs. In each of the over 10,000 tests involving the systems in the Cruze, Equinox, Terrain and Saab 9–4X vehicles, the suppression system properly characterized the occupant or CRS and enabled or disabled the air bag system, as appropriate. The same is true in the vast majority of SRX tests.

In over 5,000 of GM's SRX tests, the air bag system was enabled or disabled as desired. In just four of GM's internal (non-FMVSS) SRX tests involving three year old dummies in a particular forward facing CRSs, the suppression system enabled the air bag. In each of these tests, the CRS was installed over a 10 mm thick blanket.

These tests have no significant bearing on the present risk analysis, since more than 98 percent of the tests involving a three year old dummy in a forward-facing CRS classified correctly, and in each of the discrepant tests, the CRS would classify correctly when installed without the blanket.

There was not a single discrepancy in the over 10,000 tests involving the Cruze, Equinox, Terrain and Saab 9–4X vehicles, representing over 92 percent of the subject vehicle population. In addition, in over 99.8 percent of the SRX tests with CRSs or occupants, the air bag system was enabled or disabled, as desired, and in the remainder of the CRS tests, the air bag system was properly suppressed when the CRS was installed according to the CRS manufacturer's instructions.

The very low rate at which the conditions needed to produce the telltale error occur, coupled with the very low chance that a small child or CRS would be located in the front seat at that time, makes the potential for any safety consequence extremely small. That potential is reduced even further since it is extremely unlikely that the noncompliance condition would occur at that same time that a CRS is being installed in the vehicle, for the first time. Anyone who used such a restraint, would in all probability, have received numerous AIR BAG ON telltale illuminations before and after the infrequent noncompliant OFF illumination, and would have moved the CRS to a rear seating location or modified the installation accordingly.

GM concludes by stating that the telltale error at issue in this petition does not increase the risk to motor vehicle safety because it has no effect on occupant restraint. The air bag classification system will continue to characterize the front seat occupants and enable or disable the air bag, as designed. In addition, the noncompliance condition will rarely occur. For the error to occur at all, the vehicle must be restarted in a very particular manner within less than half of one minute of having been turned off. The conditions needed to produce the telltale error are estimated to occur approximately once every 18 months. The potential for any consequence to result is further reduced by the fact that the front seat is occupied only about a quarter of the time, and by small children and CRSs, much more infrequently. Parental and caregiver education and information in the

vehicle owner's manuals and labels warn against placing infants, children and CRSs in the front seat, and NASS data bears out that small children and CRSs are placed in the front less than one percent of the time. More importantly, GM has conducted more than 10,000 tests confirming that the air bag system in over 93 percent of the subject vehicles will properly characterize occupants and CRSs, so that the air bag will or will not be suppressed, as appropriate. With respect to the remaining vehicles, the air bag system was enabled or disabled, as desired, over 99.8 percent of the time in GM's testing. Even so, the chance that a CRS would be installed in the front seat for the first time, at the same time that the noncompliance occurred, would be even more remote.

GM has additionally informed NHTSA that it has corrected the noncompliance so that all future production vehicles will comply with FMVSS No. 208.

In summation, GM believes that the described noncompliance of its vehicles is inconsequential to motor vehicle safety, and that its petition, to exempt from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

Background Requirements: Section § 19 of FMVSS No. 208 specifically states:

§ 19 *Requirements to provide protection for infants in rear facing and convertible child restraints and car beds.*

§ 19.1 Each vehicle certified as complying with § 14 shall, at the option of the manufacturer, meet the requirements specified in § 19.2 or § 19.3, under the test procedures specified in § 20.

§ 19.2 Option 1—Automatic suppression feature. Each vehicle shall meet the requirements specified in § 19.2.1 through § 19.2.3. . . .

§ 19.2.2 The vehicle shall be equipped with at least one telltale which emits light whenever the passenger air bag system is deactivated and does not emit light whenever the passenger air bag system is activated, except that the telltale(s) need not illuminate when the passenger seat is unoccupied. Each telltale: . . .

(h) The telltale must not emit light except when the passenger air bag is turned off or during a bulb check upon vehicle starting.

NHTSA Decision: NHTSA has reviewed and accepts GM's analyses that the noncompliance is inconsequential to motor vehicle safety. GM explained that the front passenger classification and air bag suppression system complies with the safety performance requirements of the standard except under a very specific and rare set of conditions that can occur during an ignition cycle and cause the front passenger air bag OFF telltale to remain illuminated. When this occurs, the telltale is the only part of the system affected and the occupant classification system will continue to operate as designed and will enable or disable the air bag as intended. As of May 14, 2013, no consumer complaints related to this condition were received by NHTSA for the subject vehicles.

In consideration of the foregoing, NHTSA has decided that GM met its burden of persuasion that the FMVSS No. 208 noncompliance with respect to the front passenger air bag suppression status telltale lamp described in GM's Noncompliance Information Report is inconsequential to motor vehicle safety. Accordingly, GM's petition is hereby granted and the GM is exempted from the obligation of providing notification of, and a remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to the 47,554 subject vehicles that GM determined were noncompliant.

Authority: 49 U.S.C. 30118, 30120; delegations of authority at 49 CFR 1.95 and 501.8.

Issued On: June 3, 2013.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–13928 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2012–0025; Notice 2]

Bridgestone Americas Tire Operations, LLC, Grant of Petition for Decision of Inconsequential Noncompliance

AGENCY: National Highway Traffic Safety Administration, DOT.

ACTION: Grant of Petition.

SUMMARY: Bridgestone Americas Tire Operations, LLC (Bridgestone) [1], has determined that certain Firestone Transforce AT, size LT265/70R17, light truck replacement tires manufactured between November 20, 2011 and December 10, 2011, do not fully comply with paragraph § 5.5(d) of Federal Motor Vehicle Safety Standard (FMVSS) No. 139, *New Pneumatic Radial Tires for Light Vehicles.* Bridgestone has filed an appropriate report pursuant to 49 CFR part 573, *Defect and Noncompliance Responsibility and Reports,* dated January 9, 2012.

Pursuant to 49 U.S.C. 30118(d) and 30120(h) and the rule implementing those provisions at 49 CFR part 556, Bridgestone has petitioned for an exemption from the notification and remedy requirements of 49 U.S.C. Chapter 301 on the basis that this noncompliance is inconsequential to motor vehicle safety. Notice of receipt of the petition was published, with a 30-day public comment period, on April 4, 2012 in the **Federal Register** (77 FR 20482). No comments were received. To view the petition and all supporting documents log onto the Federal Docket Management System (FDMS) Web site at: *http://www.regulations.gov/.* Then follow the online search instructions to locate docket number ''NHTSA–2012–0025.''

FOR FURTHER INFORMATION CONTACT: For further information on this decision contact Mr. Jack Chern, Office of Vehicle Safety Compliance, the National Highway Traffic Safety Administration (NHTSA), telephone (202) 366–0661, facsimile (202) 366–7002.

Tires Involved: Affected are approximately 467 Firestone brand Transforce AT, size LT265/70R17, light truck replacement tires manufactured between November 20, 2011 and December 10, 2011, at the Bridgestone Canada, Inc., plant located in Uoliette, Quebec, Canada and imported into the United States by Bridgestone.

Summary of Bridgstone's Analysis and Arguments: Bridgestone explains that the noncompliance is that the sidewall marking on the intended outboard sidewall of the subject tires describes the maximum load in kilograms incorrectly. Specifically, the tires in question were inadvertently marked with a maximum load of 1350 kg. The labeling should have read 1320 kg.

Bridgestone stated its belief that the subject noncompliance is

[1] Bridgestone Americas Tire Operations, LLC is a Delaware corporation that manufactures and imports replacement equipment.

inconsequential to motor vehicle safety for the following reasons:

1. While the noncompliant tires are mislabeled; the tires do in fact have the correct marking for the maximum load in pounds on the intended outboard sidewall, and the maximum load marking in both pounds and kg is correct on the intended inboard sidewall. The tires also meet or exceed all other applicable FMVSS.

2. The subject mismarking is inconsequential as it relates to motor vehicle safety and is unlikely to have an adverse impact on motor vehicle safety since the actual performance of the subject tires will not be affected by the mismarking. Bridgestone supports this belief by stating that the tires met the performance requirements of FMVSS No. 139 for endurance and high speed when tested at the 1350 kg load.

Bridgestone also points out its belief that NHTSA has previously granted similar petitions for non-compliances in sidewall marking.

Bridgestone has additionally informed NHTSA that it has corrected the noncompliance so that all future production tires will comply with FMVSS No. 139.

In summation, Bridgestone believes that the described noncompliance of its tires to meet the requirements of FMVSS No. 139 is inconsequential to motor vehicle safety, and that its petition, to exempt from providing recall notification of noncompliance as required by 49 U.S.C. 30118 and remedying the recall noncompliance as required by 49 U.S.C. 30120 should be granted.

Requirement Background:

§ 5.5 Tire markings. Except as specified in paragraphs (a) through (i) of § 5.5, each tire must be marked on each sidewall with the information specified in § 5.5(a) through (d) and on one sidewall with the information specified in § 5.5(e) through (i) according to the phase-in schedule specified in § 7 of this standard. The markings must be placed between the maximum section width and the bead on at least one sidewall, unless the maximum section width of the tire is located in an area that is not more than one-fourth of the distance from the bead to the shoulder of the tire. If the maximum section width falls within that area, those markings must appear between the bead and a point one-half the distance from the bead to the shoulder of the tire, on at least one sidewall. The markings must be in letters and numerals not less than 0.078 inches high and raised above or sunk below the tire surface not less than 0.015 inches* * *

(d) The maximum load rating and for LT tires, the letter designating the tire load range;* * *

NHTSA'S Analysis and Decision: NHTSA believes the true measure of inconsequentiality with respect to the noncompliance with FMVSS No. 139 paragraph § 5.5(d), is whether a consumer and/or retailer who relied on the incorrect information could experience a safety problem.

In the case of this noncompliance, the subject tires are primarily sold in the domestic replacement market, where the load in pounds would be the predominant consumer unit of measurement. Thus, making the rated maximum load value marked in English units and overstated in metric unit's inconsequential to motor vehicle safety.

NHTSA has conducted a series of focus groups as required by the TREAD Act, to examine consumer perceptions and understanding of tire labeling. A few of the focus group participants had knowledge of tire labeling beyond the tire brand name, tire size, and tire pressure. Since FMVSS No. 139 applies to tires sold in the U.S., and since consumers in the U.S. overwhelmingly rely on units of English measure for loading information, the safety issue associated with overloading tires as a result of the noncompliance is very small.

NHTSA has reviewed and accepts Bridgestone's analyses that the noncompliance is inconsequential to motor vehicle safety. Bridgestone has provided sufficient documentation that the sidewall mismarkings do comply with all other safety performance requirements of the standard, except the sidewall mismarking.

In consideration of the foregoing, NHTSA has determined that Bridgestone has met its burden of persuasion that the subject FMVSS No. 139 sidewall marking noncompliance in the tires identified in Bridgestone's Noncompliance Information Report is inconsequential to motor vehicle safety. Accordingly, Bridgestone's petition is granted and Bridgestone is exempted from the obligation of providing notification of, and a remedy for, that noncompliance under 49 U.S.C. 30118 and 30120.

NHTSA notes that the statutory provisions (49 U.S.C. 30118(d) and 30120(h)) that permit manufacturers to file petitions for a determination of inconsequentiality allow NHTSA to exempt manufacturers only from the duties found in sections 30118 and 30120, respectively, to notify owners, purchasers, and dealers of a defect or noncompliance and to remedy the defect or noncompliance. Therefore, this decision only applies to approximately 467 tires that Bridgestone no longer controlled at the time that it determined that a noncompliance existed in the subject tires. However, the granting of this petition does not relieve tire distributors and dealers of the prohibitions on the sale, offer for sale, or introduction or delivery for introduction into interstate commerce of the noncompliant tires under their control after Bridgestone notified them that the subject noncompliance existed.

Authority: 49 U.S.C. 30118, 30120: delegations of authority at 49 CFR 1.95 and 501.8.

Issued On: June 5, 2013.

Claude H. Harris,

Director, Office of Vehicle Safety Compliance.

[FR Doc. 2013–13924 Filed 6–11–13; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

June 6, 2013.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before July 12, 2013 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request maybe found at *www.reginfo.gov.*

Office of Financial Stability

OMB Number: 1505–0216.

Type of Review: Extension without change of a currently approved collection.

Title: Troubled Asset Relief Program—Making Home Affordable Participants.

Abstract: Authorized under the Emergency Economic Stabilization Act (EESA) of 2008 (Public Law 110–343), the Department of the Treasury has implemented several aspects of the Troubled Asset Relief Program. Among these components is a voluntary foreclosure prevention program, Making Home Affordable (MHA) program, under which the Department will use TARP capital to lower the mortgage payments of qualifying borrowers. The Treasury will do this through agreements with mortgage servicers to modify loans on their systems. All servicers are eligible to participate in the program.

Affected Public: Private Sector: Businesses and other for-profits.

Estimated Total Burden Hours: 12,480.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2013–13883 Filed 6–11–13; 8:45 am]

BILLING CODE 4810–25–P

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

June 6, 2013.

The Department of the Treasury will submit the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, on or after the date of publication of this notice.

DATES: Comments should be received on or before July 12, 2013 to be assured of consideration.

ADDRESSES: Send comments regarding the burden estimate, or any other aspect of the information collection, including suggestion for reducing the burden, to (1) Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for Treasury, New Executive Office Building, Room 10235, Washington, DC 20503, or email at *OIRA_Submission@OMB.EOP.GOV* and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at *PRA@treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Copies of the submission(s) may be obtained by calling (202) 927–5331, email at *PRA@treasury.gov,* or the entire information collection request maybe found at *www.reginfo.gov.*

Community Development Financial Institutions (CDFI) Fund

OMB Number: 1559–0024.

Type of Review: Revision of a currently approved collection.

Title: New Markets Tax Credit (NMTC) Program Allocation Tracking System (ATS).

Abstract: The New Markets Tax Credit Program (NMTC Program) was established by Congress in 2000 to spur new or increased investments into operating businesses and real estate projects located in low-income communities. The NMTC Program attracts investment capital to low-income communities by permitting individual and corporate investors to receive a tax credit against their Federal income tax return in exchange for making equity investments in specialized financial institutions called Community Development Entities (CDEs). Via a competitive process, the Community Development Financial Institutions Fund (CDFI Fund) awards NMTC allocation awards to select CDEs, based upon information submitted in their NMTC Allocation Application. Entities receiving a NMTC allocation must enter into an allocation agreement with the CDFI Fund. The allocation agreement contains the terms and conditions, including all reporting requirements, associated with the receipt of a NMTC allocation. The CDFI Fund requires each CDE to use an electronic data collection and submission system, known as the Allocation Tracking System (ATS) to collect information on investors making Qualified Equity Investments in Community Development Entities.

The ATS enhances the allocatee's ability to report such information to the CDFI Fund in a timely fashion. This information is also used by the Treasury Department to (1) monitor the issuance of QEIs to ensure that no allocatee exceeds its allocation authority; (2) ensure that QEIs are issued within the timeframes required by the NMTC Program regulations and the legal agreements signed between the CDFI Fund and the allocatee; and (3) assist with NMTC Program evaluation efforts.

Affected Public: State, Local, and Tribal Governments; Private Sector: Businesses or other for-profits, Not-for-profit institutions.

Estimated Annual Burden Hours: 9,426.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2013–13884 Filed 6–11–13; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Amendment—Liberty Mutual Insurance Company

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 9 to the Treasury Department Circular 570, 2012 Revision, published July 2, 2012, at 77 FR 39322.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: The underwriting limitation for the following company has been amended:

Liberty Mutual Insurance Company (NAIC # 23043), which was listed in the Treasury Department Circular 570, published on July 2, 2012, is hereby amended to read $1,145,803,000.

Federal bond-approving officers should annotate their reference copies of the Treasury Department Circular 570 (''Circular''), 2012 Revision, to reflect this change.

The Circular may be viewed and downloaded through the Internet at *www.fms.treas.gov/c570.*

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Bureau of the Fiscal Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: June 3, 2013.

Kevin McIntyre,

Acting Director, Financial Accounting and Services Division.

[FR Doc. 2013–13921 Filed 6–11–13; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Amendment—Safeco Insurance Company of America

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 10 to the Treasury Department Circular 570, 2012 Revision, published July 2, 2012, at 77 FR 39322.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: The underwriting limitation for the following company has been amended:

Safeco Insurance Company of America (NAIC #24740), which was listed in the Treasury Department Circular 570, published on July 2, 2012, is hereby amended to read $87,081,000.

Federal bond-approving officers should annotate their reference copies of the Treasury Department Circular 570 (''Circular''), 2012 Revision, to reflect this change.

The Circular may be viewed and downloaded through the Internet at *www.fms.treas.gov/c570.*

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Bureau of the Fiscal Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: June 3, 2013.

Kevin McIntyre,

Acting Director, Financial Accounting and Services Division.

[FR Doc. 2013–13916 Filed 6–11–13; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Name Change—Allied World Reinsurance Company (NAIC# 22730)

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 11 to the Treasury Department Circular 570, 2012 Revision, published July 2, 2012, at 77 FR 39322.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: Notice is hereby given that Allied World Reinsurance Company (NAIC# 22730) has formally changed its name to Allied World Insurance Company effective December 11, 2012. Federal bond-approving officials should annotate their reference copies of the Treasury Department Circular 570 (''Circular''), 2012 Revision, to reflect this change.

The Circular may be viewed and downloaded through the Internet at *www.fms.treas.gov/c570.*

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Bureau of the Fiscal Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: June 1, 2013.

Kevin McIntyre,

Acting Director, Financial Accounting and Services Division, Financial Management Service.

[FR Doc. 2013–13932 Filed 6–11–13; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Terminations—American Economy Insurance Company (NAIC# 19690); American States Insurance Company (NAIC# 19704); General Insurance Company of America (NAIC# 24732)

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 7 to the Treasury Department Circular 570, 2012 Revision, published July 2, 2012, at 77 FR 39322.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Certificates of Authority issued by the Treasury to the above-named companies under 31 U.S.C. 9305 to qualify as acceptable sureties on Federal bonds are terminated effective immediately. Federal bond-approving officials should annotate their reference copies of the Treasury Department Circular 570 (Circular), 2012 Revision, to reflect this change.

With respect to any bonds currently in force with these companies, bond-approving officers may let such bonds run to expiration and need not secure new bonds. However, no new bonds should be accepted from these companies, and bonds that are continuous in nature should not be renewed.

The Circular may be viewed and downloaded through the Internet at *www.fms.treas.gov/c570.*

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Bureau of the Fiscal Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: June 3, 2013.

Kevin McIntyre,

Acting Director, Financial Accounting and Services Division.

[FR Doc. 2013–13927 Filed 6–11–13; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Fiscal Service

Surety Companies Acceptable on Federal Bonds: Terminations—Safeco Insurance Company of Illinois (NAIC# 39012); Safeco National Insurance Company (NAIC# 24759)

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Department of the Treasury.

ACTION: Notice.

SUMMARY: This is Supplement No. 8 to the Treasury Department Circular 570, 2012 Revision, published July 2, 2012, at 77 FR 39322.

FOR FURTHER INFORMATION CONTACT: Surety Bond Branch at (202) 874–6850.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Certificates of Authority issued by the Treasury to the above-named companies under 31 U.S.C. 9305 to qualify as acceptable sureties on Federal bonds are terminated effective immediately. Federal bond-approving officials should annotate their reference copies of the Treasury Department Circular 570 (''Circular''), 2012 Revision, to reflect this change.

With respect to any bonds currently in force with these companies, bond-approving officers may let such bonds run to expiration and need not secure new bonds. However, no new bonds should be accepted from these companies, and bonds that are continuous in nature should not be renewed.

The Circular may be viewed and downloaded through the Internet at *www.fms.treas.gov/c570.*

Questions concerning this notice may be directed to the U.S. Department of the Treasury, Bureau of the Fiscal Service, Financial Accounting and Services Division, Surety Bond Branch, 3700 East-West Highway, Room 6F01, Hyattsville, MD 20782.

Dated: June 3, 2013.

Kevin McIntyre,

Acting Director, Financial Accounting and Services Division.

[FR Doc. 2013–13925 Filed 6–11–13; 8:45 am]

BILLING CODE 4810–35–M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 1099–DIV

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 1099–DIV, Dividends and Distributions.

DATES: Written comments should be received on or before August 12, 2013 to be assured of consideration.

ADDRESSES: Direct all written comments to R. Joseph Durbala. Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Katherine Dean at Internal Revenue Service, Room 6242, 1111 Constitution Avenue NW., Washington, DC 20224, or at (202) 622–3186, or through the Internet at *Katherine.b.dean@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Dividends and Distributions.

OMB Number: 1545–0110.

Form Number: 1099–DIV.

Abstract: Form 1099–DIV is used by the IRS to insure that dividends are properly reported as required by Internal Revenue Code section 6042, that liquidation distributions are correctly reported as required by Code section 6043, and to determine whether payees are correctly reporting their income.

Current Actions: Five line items are added to capture state income tax information for the convenience of the taxpayer. These boxes are optional, and not processed by the IRS. The addition of these lines, offset by a decrease in the estimated responses (to 79,134,5000) will result in an estimated annual burden increase of 6,330,760 hours.

Type of Review: Revision of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 79,134,500.

Estimated Time per Response: 23 minutes.

Estimated Total Annual Burden Hours: 30,962,455

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: June 5, 2013.

R. Joseph Durbala,

OMB Reports Clearance Officer.

[FR Doc. 2013–13880 Filed 6–11–13; 8:45 am]

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Part II

Department of the Interior

Fish and Wildlife Service

50 CFR Part 18

Marine Mammals; Incidental Take During Specified Activities; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 18

[Docket No. FWS–R7–ES–2012–0043; FF07CAMM00–FXFR133707PB000]

RIN 1018–AY67

Marine Mammals; Incidental Take During Specified Activities

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: In accordance with the Marine Mammal Protection Act of 1972, as amended (MMPA), and its implementing regulations, we, the U.S. Fish and Wildlife Service (Service or we), are finalizing regulations that authorize the nonlethal, incidental, unintentional take of small numbers of Pacific walruses (*Odobenus rosmarus divergens*) and polar bears (*Ursus maritimus*) during oil and gas Industry (Industry) exploration activities in the Chukchi Sea and adjacent western coast of Alaska. This rule is effective for 5 years from the date of issuance.

The total expected takings of Pacific walruses (walruses) and polar bears during Industry exploration activities will impact small numbers of animals, will have a negligible impact on these species, and will not have an unmitigable adverse impact on the availability of these species for subsistence use by Alaska Natives. These final regulations include: Permissible methods of nonlethal taking; measures to ensure that Industry activities will have the least practicable adverse impact on the species and their habitat, and on the availability of these species for subsistence uses; and requirements for monitoring and reporting of any incidental takings that may occur, to the Service. The Service will issue Letters of Authorization (LOAs), upon request, for activities proposed to be conducted in accordance with the regulations.

DATES: This rule is effective June 12, 2013, and remains effective through June 12, 2018.

ADDRESSES: The final rule and associated environmental assessment (EA) are available for viewing at *http://www.regulations.gov* at Docket No. FWS–R7–ES–2012–0043.

Comments and materials received in response to this action are available for public inspection during normal working hours of 8 a.m. to 4:30 p.m., Monday through Friday, at the Marine Mammals Management Office, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, AK 99503.

FOR FURTHER INFORMATION CONTACT: Craig Perham, Marine Mammals Management Office, U.S. Fish and Wildlife Service, Region 7, 1011 East Tudor Road, Anchorage, AK 99503; telephone: 907–786–3800 or 1–800–362–5148. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, 24 hours a day, 7 days a week.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why We Need To Publish a Final Rule

Incidental take regulations (ITRs), under section 101(a)(5)(A) of the MMPA, allow for incidental, but not intentional, take of small numbers of marine mammals that may occur during the conduct of otherwise lawful activities within a specific geographical region. If the public requests that the ITRs be issued, the Service must first determine that the total of such taking during each 5-year (or less) period concerned will have a negligible impact on marine mammals and will not have an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses by Alaska Natives. The Service has considered a request from Industry to issue ITRs in the Chukchi Sea for a 5-year period to allow for the nonlethal, incidental taking of polar bears or walruses during their exploration activities. The Service is issuing these ITRs based on our determination that potential impacts to polar bears and Pacific walruses will be negligible and the potential impacts to subsistence use of polar bears and Pacific walruses are mitigable.

What is the effect of this final rule?

These ITRs provide a mechanism for the Service to work with Industry to minimize the effects of Industry activity on marine mammals through appropriate mitigation and monitoring measures, which also provide important information on marine mammal distribution, behavior, movements, and interactions with Industry. Additionally, these regulations provide a mechanism whereby persons conducting oil and gas exploration activities in the specified area in accordance with the terms of an LOA issued pursuant to these regulations will not be subject to criminal or civil prosecution under the MMPA.

The Basis for Our Action

Based upon our review of the nature, scope, and timing of the oil and gas exploration activities and mitigation measures, and in consideration of the best available scientific information, it is our determination that the activities will have a negligible impact on walruses and on polar bears and will not have an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses by Alaska Natives.

Effective Date

In accordance with 5 U.S.C. 553(d)(3), we find that we have good cause to make this rule effective less than 30 days after publication (see **DATES**). Making this rule effective immediately upon publication will ensure that Industry implements mitigation measures and monitoring programs in the geographic region that reduce the risk of lethal and nonlethal effects to polar bears and Pacific walruses by Industry activities.

Background

Section 101(a)(5)(A) of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1371(a)(5)(A)) gives the Secretary of the Interior (Secretary), through the Director of the Service, the authority to allow the incidental, but not intentional, taking of small numbers of marine mammals, in response to requests by U.S. citizens [as defined in 50 CFR 18.27(c)] engaged in a specified activity (other than commercial fishing) in a specified geographic region. According to the MMPA, the Service shall allow this incidental taking if (1) we make a finding that the total of such taking for the 5-year timeframe of the regulations will have no more than a negligible impact on these species and will not have an unmitigable adverse impact on the availability of these species for taking for subsistence use by Alaska Natives, and (2) we issue regulations that set forth (i) permissible methods of taking, (ii) means of effecting the least practicable adverse impact on the species and their habitat and on the availability of the species for subsistence uses, and (iii) requirements for monitoring and reporting. If we issue regulations allowing such incidental taking, we can issue LOAs to conduct activities under the provisions of these regulations when requested by citizens of the United States.

The term ''take,'' as defined by the MMPA, means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. Harassment, as defined by the MMPA, for activities other than military readiness activities or scientific research conducted by or on behalf of the Federal Government, means ''any act of pursuit,

torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild'' [the MMPA calls this Level A harassment] ''or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering'' [the MMPA calls this Level B harassment] (16 U.S.C. 1362).

The terms ''negligible impact'' and ''unmitigable adverse impact'' are defined at 50 CFR 18.27 as follows. ''Negligible impact'' is ''an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

''Unmitigable adverse impact'' means ''an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by (i) causing the marine mammals to abandon or avoid hunting areas, (ii) directly displacing subsistence users, or (iii) placing physical barriers between the marine mammals and the subsistence hunters; and (2) that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.'' The term ''small numbers'' is also defined in the regulations, but we do not rely on that definition here as it conflates the ''small numbers'' and ''negligible impact'' requirements, which we recognize as two separate and distinct requirements for promulgating ITRs under the MMPA. Instead, in our small numbers determination, we evaluate whether the number of marine mammals likely to be taken is small relative to the size of the overall population.

Industry conducts activities, such as oil and gas exploration, in marine mammal habitat that could result in the incidental taking of marine mammals. Although Industry is under no legal requirement under the MMPA to obtain incidental take authorization, since 1991, Industry has requested, and we have issued regulations for, incidental take authorization for conducting activities in areas of walrus and polar bear habitat. We issued ITRs for walruses and polar bears in the Chukchi Sea for the period from 1991 to 1996 (56 FR 27443; June 14, 1991) and 2008 to 2013 (73 FR 33212; June 11, 2008). These regulations are at 50 CFR part 18, subpart I (§§ 18.111 to 18.119). In the Beaufort Sea, ITRs have been issued from 1993 to present: November 16, 1993 (58 FR 60402); August 17, 1995 (60 FR 42805); January 28, 1999 (64 FR 4328); February 3, 2000 (65 FR 5275); March 30, 2000 (65 FR 16828); November 28, 2003 (68 FR 66744); August 2, 2006 (71 FR 43926), and August 3, 2011 (76 FR 47010). These regulations are at 50 CFR part 18, subpart J (§§ 18.121 to 18.129).

Summary of Current Request

On January 31, 2012, the Alaska Oil and Gas Association (AOGA), on behalf of its members, and ConocoPhillips, Alaska, Inc. (CPAI), a participating party, requested that the Service promulgate regulations to allow the nonlethal, incidental take of small numbers of walruses and polar bears in the Chukchi Sea and the adjacent western coast of Alaska. AOGA requested that the regulations be applicable to all persons conducting activities associated with oil and gas exploration as described in its petition for a period of 5 years. AOGA is a private, nonprofit trade association representing companies active in the Alaska oil and gas Industry. AOGA's members include: Alyeska Pipeline Service Company, Apache Corporation, BP Exploration (Alaska) Inc., Chevron, Eni Petroleum, ExxonMobil Production Company, Flint Hills Resources, Inc., Hilcorp Alaska, LLC, Marathon Oil Company, Petro Star Inc., Pioneer Natural Resources Alaska, Inc., Repsol, Shell Gulf of Mexico, Inc., Statoil, Tesoro Alaska Company, and XTO Energy, Inc.

The 2012 request was for regulations to allow the incidental, nonlethal take of small numbers of walruses and polar bears in association with oil and gas activities in the Chukchi Sea and adjacent coastline for the period from June 11, 2013, to June 11, 2018. The information provided by the petitioners indicates that projected oil and gas activities over this timeframe will be limited to exploration activities. Within that time, oil and gas exploration activities could occur during any month of the year, depending on the type of activity. Offshore activities, such as exploration drilling, seismic surveys, and shallow hazards surveys, are expected to occur only during the open-water season (July–November). Onshore activities may occur during winter (e.g., geotechnical studies), spring (e.g., hydrological studies), or summer–fall (e.g., various fish and wildlife surveys). The petitioners have also specifically requested that these regulations be issued for nonlethal take. The petitioners have indicated that, through the implementation of appropriate mitigation measures, they are confident that no lethal take will occur.

Prior to issuing these regulations in response to this request, we evaluated the level of industrial activities, their associated potential impacts to walruses and polar bears, and their effects on the availability of these species for subsistence use. All projected exploration activities described by CPAI and AOGA (on behalf of its members) in their petition, as well as projections of reasonably likely activities for the period 2013 to 2018, were considered in our analysis. The activities and geographic region specified in the request, and considered in these regulations, are described in the ensuing sections titled ''Description of Geographic Region'' and ''Description of Activities.''

Description of Final Regulations

The regulations include: Permissible methods of nonlethal taking; measures to ensure the least practicable adverse impact on the species and the availability of these species for subsistence uses; and requirements for monitoring and reporting. These regulations do not authorize, or ''permit,'' the actual activities associated with oil and gas exploration, e.g., seismic testing, drilling, or sea floor mapping. Rather, they authorize the nonlethal, incidental, unintentional take of small numbers of polar bears and walruses associated with those activities based on standards set forth in the MMPA. The Bureau of Ocean Energy Management (BOEM), the Bureau of Safety and Environmental Enforcement (BSEE), the U.S. Army Corps of Engineers (COE), and the Bureau of Land Management (BLM) are responsible for permitting activities associated with oil and gas activities in Federal waters and on Federal lands. The State of Alaska is responsible for permitting activities on State lands and in State waters.

Under these final regulations, persons may seek taking authorization for particular projects by applying to the Service for an LOA for the incidental, nonlethal take associated with exploration activities pursuant to the regulations. Each group or individual conducting an Industry-related activity within the area covered by these regulations will be able to request an LOA. Applicants for LOAs will have to submit an Operations Plan for the activity, a marine mammal (Pacific walrus and polar bear) interaction plan, and a site-specific marine mammal monitoring and mitigation plan to monitor any effects of authorized activities on walruses and polar bears.

An after-action report on exploration activities and marine mammal monitoring activities will have to be submitted to the Service within 90 days after completion of the activity. Details of monitoring and reporting requirements are further described in ''Potential Effects of Oil and Gas Industry Activities on Pacific Walruses and Polar Bears.''

Applicants will also have to include a Plan of Cooperation (POC) describing the availability of these species for subsistence use by Alaska Native communities and how that availability may be affected by Industry operations. The purpose of the POC is to ensure that oil and gas activities will not have an unmitigable adverse impact on the availability of the species or the stock for subsistence uses. The POC must provide the procedures on how Industry will work with the affected Alaska Native communities, including a description of the necessary actions that will be taken to: (1) Avoid or minimize interference with subsistence hunting of polar bears and walruses; and (2) ensure continued availability of the species for subsistence use. The POC is further described in ''Potential Effects of Oil and Gas Industry Activities on Subsistence Uses of Pacific Walruses and Polar Bears.''

Under these final regulations, we will evaluate each request for an LOA based on the specific activity and specific location, and may condition the LOA depending on specific circumstances for that activity and location. More information on applying for and receiving an LOA can be found at 50 CFR 18.27(f).

Description of Geographic Region

These regulations allow Industry operators to incidentally take small numbers of walruses and polar bears within the area, hereafter referred to as the Chukchi Sea region (Figure 1; see Final Regulation Promulgation section). The geographic area covered by AOGA's request is the Outer Continental Shelf (OCS) of the Arctic Ocean adjacent to western Alaska. This area includes the waters (State of Alaska and OCS waters) and seabed of the Chukchi Sea, which encompasses all waters north and west of Point Hope (68°20′20″ N, −166°50′40 W, BGN 1947) to the U.S.–Russia Convention Line of 1867, west of a north–south line through Point Barrow (71°23′29″ N, −156°28′30 W, BGN 1944), and up to 200 miles north of Point Barrow. The Chukchi Sea region includes that area defined as the BOEM/BSEE OCS oil and gas Lease Sale 193 in the Chukchi Sea Planning Area. The Chukchi Sea region also includes the terrestrial coastal land 25 miles inland between the western boundary of the south National Petroleum Reserve–Alaska (NPR–A) near Icy Cape (70°20′00″, −148°12′00) and the north–south line from Point Barrow. The Chukchi Sea region encompasses an area of approximately 240,000 square kilometers (km) (approximately 92,644 square miles). The terrestrial portion of the Chukchi Sea region encompasses approximately 10,000 km² (3,861 mi²) of the Northwest and South Planning Areas of the National Petroleum Reserve–Alaska (NPR–A). The north–south line at Point Barrow is the western border of the geographic region in the Beaufort Sea incidental take regulations (August 3, 2011; 76 FR 47010).

Description of Activities

These final regulations cover exploratory drilling, seismic surveys, geotechnical surveys, and shallow hazards surveys to be conducted in the Chukchi Sea from June 11, 2013, to June 11, 2018. This time period includes the entire open-water seasons of 2013 through 2017, when activities such as exploration drilling, seismic surveys, geotechnical surveys, and shallow hazards surveys are likely to occur, but terminates before the start of the 2018 open-water season.

This section reviews the types and scale of oil and gas activities projected to occur in the Chukchi Sea region over the specified time period (2013 to 2018). Activities covered in these regulations include Industry exploration operations of oil and gas reserves, as well as environmental monitoring associated with those activities, on the western coast of Alaska and the Outer Continental Shelf of the Chukchi Sea. This information is based upon activity descriptions provided by the petitioners (sections 2.2 and 2.3 of the AOGA *Petition for Incidental Take Regulations for Oil and Gas Activities in the Chukchi Sea and Adjacent Lands in 2013 to 2018,* January 31, 2012). These regulations are also based on additional activities in the Chukchi Sea region that the Service identified and deemed similar to the type requested in the petition. In including additional information, the Service has used its discretion, in conducting its analysis, to assess the potential impacts that more frequent activities may have on polar bears or Pacific walruses. For example, we chose to analyze the potential impacts of two annual seismic operations on polar bears and Pacific walruses, rather than the requested one seismic operation, to allow incidental take coverage in the event that more seismic survey activities actually occur annually than what the petitioners requested. If LOAs are requested for activities that exceed the scope of activities analyzed under these final regulations, the LOAs will not be issued, and the Service will consider the potential use of other management tools to reduce take under different provisions of the MMPA or reevaluate its findings before further LOAs are issued.

As discussed above, these ITRs apply from June 12, 2013, and remain effective through June 12, 2018. Within that time, oil and gas exploration activities could occur during any month of the year, depending on the type of activity. Offshore activities, such as exploration drilling, seismic surveys, and shallow hazards surveys, are expected to occur only during the open-water season (July–November). Onshore activities may occur during winter (e.g., geotechnical studies), spring (e.g., hydrological studies), or summer–fall (e.g., various fish and wildlife surveys).

Specific locations, within the designated geographic region, where oil and gas exploration will occur will be determined based upon a variety of factors, including the outcome of future Federal and State oil and gas lease sales and information gathered through subsequent rounds of exploration discovery. The information provided by the petitioners indicates that offshore exploration activities will be carried out during the open-water season to avoid seasonal pack ice. Further onshore activities will be limited and are not expected to occur in the vicinity of known polar bear denning areas or coastal walrus haulouts.

These ITRs do not authorize the execution, placement, or location of Industry activities; they only authorize incidental, nonlethal take of walruses and polar bears that may result during the course of Industry activities. Authorizing the activity at particular locations is part of the permitting process that is authorized by the lead permitting agency, such as BOEM/BSEE, the COE, or BLM. The specific dates and durations of the individual operations and their geographic locations are provided to the Service in detail when requests for LOAs are submitted.

Oil and gas activities anticipated and considered in our analysis of these final ITRs include: (1) Offshore exploration drilling; (2) offshore 3D and 2D seismic surveys; (3) shallow hazards surveys; (4) other geophysical surveys, such as ice gouge, strudel scour, and bathymetry surveys; (5) geotechnical surveys; (6) onshore and offshore environmental studies; and (7) associated support

activities for the aforementioned activities. Of these, offshore drilling and seismic surveys are expected to have the greatest potential effects on Pacific walruses, polar bears, and Alaska Native subsistence activities. A summary description of the anticipated activities follows, while detailed descriptions provided by the petitioners are available on the Service's Marine Mammals Management Web page at: *http://alaska.fws.gov/fisheries/mmm/itr.htm.*

Offshore Exploration Drilling

Offshore exploration drilling will be conducted from either a floating drilling unit, such as a drillship or conical drilling unit, or a jack-up drilling platform. The operating season for exploration drilling with these types of drilling units is expected to be limited to the open-water season, from July 1 through November 30, when the presence of ice is at a minimum. Petitioners indicate that bottom-founded platforms will not be used during exploration activities due to water depths greater than 30 meters (m) (100 feet [ft]) and possible pack ice incursions. Drilling operations are expected to range between 30 and 90 days at individual well sites, depending on the depth to the target formation, and difficulties during drilling. The drilling units and any support vessels typically enter the Chukchi Sea at the beginning of the season and exit the sea at the end of the season. Drillships are generally self-propelled, whereas jack-up rigs must be towed to the drill site. These drilling units are largely self-contained with accommodations for the crew, including quarters, galleys, and sanitation facilities.

Drilling operations will include multiple support vessels in addition to the drillship or platform, including ice management vessels, survey vessels, and on and offshore support facilities. For example, each drillship is likely to be supported by one to two ice management vessels, a barge and tug, one to two helicopter flights per day, and one to two supply ships per week. Ice management is expected to be required for only a small portion of the drilling season, if at all, given the lack of sea ice observed over most current lease holdings in the Chukchi Sea region in recent years. Most ice management will consist of actively pushing the ice off its trajectory with the bow of the ice management vessel, but some icebreaking could be required. One or more ice management vessels generally support drillships to ensure ice does not encroach on operations. Geophysical surveys referred to as vertical seismic profiles (VSPs) will likely be conducted at many of the Chukchi Sea region drill sites where and when an exploration well is being drilled. The purpose of such surveys is to ground truth existing seismic data with geological information from the wellbore. A small airgun array is deployed at a location near or adjacent to the drilling unit, and receivers are placed (temporarily anchored) in the wellbore. Exploration drilling programs may entail both onshore support facilities for air support where aircraft serving crew changes, search and rescue, and/or re-supply functions where support facilities will be housed and marine support where vessels may access the shoreline. For offshore support purposes, a barge and tug typically accompany the vessels to provide a standby safety vessel, oil spill response capabilities, and refueling support. Most supplies (including fuel) necessary to complete drilling activities are stored on the drillship and support vessels. Helicopter servicing of drillships can occur as frequently as one to two times per day.

Since 1989, five exploration wells have been drilled in the Chukchi Sea. Based upon information provided by the petitioners, we estimate that up to three operators will drill a total of three to eight wells per year in the Chukchi Sea region during the 5-year timeframe of these final regulations (June 2013 to June 2018).

Offshore 2D and 3D Seismic Surveys

Seismic survey equipment includes sound energy sources (airguns) and receivers (hydrophones/geophones). The airguns store compressed air that upon release forms a bubble that expands and contracts in a predictable pattern, emitting sound waves. The sound energy from the source penetrates the seafloor and is reflected back to the surface where it is recorded and analyzed to produce graphic images of the subsurface features. Differences in the properties of the various rock layers found at different depths reflect the sound energy at different positions and times. This reflected energy is received by the hydrophones housed in submerged streamers towed behind the survey vessel.

The two general types of offshore seismic surveys, 2D and 3D surveys, use similar technology but differ in survey transect patterns, number of transects, number of sound sources and receptors, and data analysis. For both types, a group of air guns is usually deployed in an array to produce a downward focused sound signal. Air gun array volumes for both 2D and 3D seismic surveys are expected to range from 49,161 to 65,548 cm^3 (3,000 to 4,000 in^3) operated at about 2,000 pounds per square inch (psi) (13,789.5 kilopascal [kPa]). The air guns are fired at short, regular intervals, so the arrays emit pulsed rather than continuous sound. While most of the energy is focused downward and the short duration of each pulse limits the total energy into the water column, the sound can propagate horizontally for several kilometers.

Marine streamer 2D surveys use similar geophysical survey techniques as 3D surveys, but both the mode of operation and general vessel type used are different. The primary difference between the two survey types is that a 3D survey has a denser grid for the transect pattern. The 2D surveys provide a less detailed subsurface image because the survey lines are spaced farther apart, but they are generally designed to cover wider areas to image geologic structure on more of a regional basis. Large prospects are easily identified on 2D seismic data, but detailed images of the prospective areas within a large prospect can only be seen using 3D data. The 2D seismic survey vessels generally are smaller than 3D survey vessels, although larger 3D survey vessels are also capable of conducting 2D surveys. The 2D source array typically consists of three or more sub-arrays of six to eight air gun sources each. The sound source level (zero-to-peak) associated with 2D marine seismic surveys are the same as 3D marine seismic surveys (233 to 240 dB re 1 μPa at 1 m). Typically, a single hydrophone streamer cable approximately 8 to 12 km (~5 to 7.5 miles [mi]) long is towed behind the survey vessel. The 2D surveys acquire data along single track lines that are spread more widely apart (usually several km) than are track lines for 3D surveys (usually several hundred meters).

A 3D source array typically consists of two to three sub-arrays of six to nine air guns each, and is about 12.5 to 18 m (41 to 59 ft) long and 16 to 36 m (52.5 to 118 ft) wide. The size of the source array can vary during the seismic survey to optimize the resolution of the geophysical data collected at any particular site. Most 3D operations use a single source vessel; however, in a few instances, more than one source vessel may be used. The sound source level (zero-to-peak) associated with typical 3D seismic surveys ranges between 233 and 240 decibels (dB) at 1 m (dB re 1 μPa at 1 m).

The receiving arrays could include multiple (4 to 16) streamer receiver cables towed behind the source array. The survey vessel may tow up to 12

cables, or streamers, of up to 8.0 km (5.0 mi) in length, spaced 50 to 150 m (164 to 492 ft) apart. Streamer cables contain numerous hydrophone elements at fixed distances within each cable. Each streamer can be 3 to 8 km (2 to 5 mi) long with an overall array width of up to 1,500 m (1,640 yards) between outermost streamer cables. The wide extent of this towed equipment limits both the turning speed and the area a vessel covers with a single pass over a geologic target. It is, therefore, common practice to acquire data using an offset racetrack pattern. Adjacent transit lines for a survey generally are spaced several hundred meters apart and are parallel to each other across the survey area. Seismic surveys are conducted day and night when ocean conditions are favorable, and one survey effort may continue for weeks or months throughout the open-water season, depending on the size of the survey. Data acquisition is affected by the arrays towed by the survey vessel and weather conditions. Typically, data are only collected between 25 and 30 percent of the time (or 6 to 8 hours a day) because of equipment or weather problems. In addition to downtime due to weather, sea conditions, turning between lines, and equipment maintenance, surveys could be suspended to avoid interactions with biological resources. In the past, BOEM/BSEE has estimated that individual surveys could last between 20 to 30 days (with downtime) to cover a 322-km^2 (200-mi^2) area.

Both 3D and 2D seismic surveys require a largely ice-free environment to allow effective operation and maneuvering of the air gun arrays and long streamers. In the Chukchi Sea region, the timing and areas of the surveys will be dictated by ice conditions. Given optimal conditions, the data acquisition season in the Chukchi Sea could start sometime in July and end sometime in early November. Even during the short summer season, there are periodic incursions of sea ice; hence there is no guarantee that any given location will be ice-free throughout the survey.

In our analysis of the previous 5-year Chukchi Sea regulations (2008–2013), we determined that up to three seismic programs operating annually, totaling up to 15 surveys over the span of the regulations, would have negligible effects on small numbers of walruses and polar bears. Since 2006, only seven seismic surveys have been actually conducted in total in the Chukchi Sea. For the 5-year time period of the regulations we are promulgating today (2013 to 2018), based upon information provided by the petitioners, the Service estimates that, in any given year one seismic survey program (2D or 3D) would operate in the Chukchi Sea region during the open-water season. However, to be more comprehensive the Service analyzed an annual estimate of two simultaneous seismic operations in the Chukchi Sea region during the open-water season. We further estimate that each seismic survey vessel will be accompanied or serviced by one to three support vessels, and that helicopters may also be used for vessel support and crew changes.

Shallow Hazards Surveys

Shallow hazards surveys in the Chukchi Sea region are expected to be conducted for all OCS leases in the Chukchi Sea Planning Area. Shallow hazards surveys, also known as site clearance or high resolution surveys, are conducted to collect bathymetric data and information on the shallow geology down to depths of about 450 m (1,500 ft) below the seafloor at areas identified as potential drill sites. Detailed maps of the seafloor surface and shallow sub-surface are produced with the resulting data in order to identify potential hazards in the area. Shallow hazards surveys must be conducted at all exploration drill sites in the OCS before drilling can be approved by BOEM/BSEE. Specific requirements for these shallow hazards surveys are presented in BOEM/BSEE's Notice to Lessee (NTL) 05–A01. Potential hazards may include: Shallow faults; shallow gas; permafrost; hydrates; and/or archaeological features, such as shipwrecks. Drilling permits will only be issued by the BOEM/BSEE for locations that avoid or minimize any risks of encountering these types of features.

Equipment used in past surveys included sub-bottom profilers, multi-beam bathymetric sonar, side scan sonar, high resolution seismic (airgun array or sparker), and magnetometers. Equipment to be used in future surveys in 2013 to 2018 will be expected to be these and similar types of equipment as required by the BOEM/BSEE NTLs.

Shallow hazards surveys are conducted from vessels during the summer or open-water season along a series of transects, with different line spacing depending on the proximity to the proposed drill site and geophysical equipment to be used. Generally, a single vessel is required to conduct the survey, but in the Chukchi Sea an additional vessel is often used as a marine mammal monitoring platform. The geophysical equipment is either hull mounted or towed behind the vessel, and sometimes is located on an autonomous underwater vehicle (AUV). Small airgun arrays with a total volume of 258 cm^3 (40 in^3) and pressured to about 2,000 psi (13,789.5 kPa) have been used as the energy source for past high resolution seismic surveys and will be expected to be used in future surveys in 2013 to 2018, but larger or smaller airguns under more or lesser pressure may be used. Sparkers have also been used in the Chukchi Sea in the past and may be used in the future. The magnetometer is used to locate and identify any human-made ferrous objects that might be on the seafloor.

During the period of the previous regulations (2008 to 2013), four shallow hazards and site clearance surveys were actually conducted. Based upon information provided by the petitioners, we estimate that during the timeframe of these regulations (2013 to 2018), up to two operators will conduct from four to seven shallow hazards surveys annually.

Marine Geophysical Surveys

Additional types of geophysical surveys are also expected to occur. These include ice gouge surveys, strudel scours surveys, and other bathymetric surveys (e.g., platform and pipeline surveys). These surveys use the same types of remote sensing geophysical equipment used in shallow hazards surveys, but they are conducted for different purposes in different areas and often lack a seismic (airgun) component. Each of these types of surveys is briefly described below.

Ice Gouge Surveys

Ice gouging is the creation of troughs and ridges on the seafloor caused by the contact of the keels of moving ice floes with unconsolidated sediments on the seafloor. Oil and gas operators conduct these surveys to gain an understanding of the distribution, frequency, size, and orientation of ice gouging in their areas of interest in order to predict the location, size, and frequency of future ice gouging. The surveys may be conducted from June through October when the area is sufficiently clear of ice and weather permits. Equipment to be used in ice gouge surveys during this time may include, but may not be limited to, sub-bottom profilers, multi-beam bathymetric sonar, and side scan sonar.

Strudel Scour Surveys

Strudel scours are formed in the seafloor during a brief period in the spring when river discharge commences the breakup of the sea ice. The ice is bottom fast, with the river discharge flowing over the top of the ice. The overflow spreads offshore and drains

through the ice sheet at tidal cracks, thermal cracks, stress cracks, and seal breathing holes reaching the seafloor with enough force to generate distinctive erosion patterns. Oil and gas operators conduct surveys to identify locations where this phenomenon occurs and to understand the process. Nearshore areas (State waters) by the larger rivers are first surveyed from the air with a helicopter at the time when rivers are discharging on to the sea ice (typically in May), to identify any locations where the discharge is moving through the ice. The identified areas are revisited by vessel during the open-water season (typically July to October), and bathymetric surveys are conducted along a series of transects over the identified areas. Equipment to be used in the surveys in 2013 to 2018 will likely include, but may not be limited to, multi-beam bathymetric sonar, side scan sonar, and single beam bathymetric sonar.

Bathymetry Surveys

Some surveys are expected to determine the feasibility of future development. This effort will include siting such things as pipeline and platform surveys. These surveys use geophysical equipment to delineate the bathymetry/seafloor relief and characteristics of the surficial seafloor sediments. The surveys are conducted from vessels along a series of transects. Equipment deployed on the vessel for these surveys will likely include, but may not be limited to, sub-bottom profilers, multi-beam bathymetric sonar, side scan sonar, and magnetometers.

Based upon information provided by the petitioners, we estimate that up to two operators will conduct as many as two geophysical surveys, including ice gouge, strudel scour, and bathymetry surveys, in any given year during the 5-year timeframe of these regulations (2013 to 2018).

Geotechnical Surveys

Geotechnical surveys expected to occur within the Chukchi Sea region take place offshore on leases in federal waters of the OCS and adjacent onshore areas. Geotechnical site investigations are performed to collect detailed data about seafloor sediments, onshore soil, and shallow geologic structures. During site investigations, boreholes are drilled to depths sufficient to characterize the soils within the zone of influence. The borings, cores, or cone penetrometer data collected at the site define the stratigraphy and geotechnical properties at that specific location. These data are analyzed and used in determining optimal facility locations. Site investigations that include archaeological, biological, and ecological data assist in the development of foundation design criteria for any planned structure. Methodology for geotechnical surveys may vary between those conducted offshore and onshore. Onshore geotechnical surveys will likely be conducted in winter when the tundra is frozen. Rotary drilling equipment will be wheeled, tracked, or sled mounted. Offshore geotechnical studies will be conducted from dedicated vessels or support vessels associated with other operations such as drilling.

Based upon information provided by the petitioners, we estimate that as many as two operators will conduct up to two geotechnical surveys in any given year during the 5-year timeframe of these regulations (2013 to 2018).

Offshore Environmental Studies

Offshore environmental studies are likely to include: Ecological surveys of the benthos, plankton, fish, bird, and marine mammal communities and use of Chukchi Sea waters; acoustical studies of marine mammals; sediment and water quality analysis; and physical oceanographic investigations of sea ice movement, currents, and meteorology. Most bird and marine mammal surveys will be conducted from vessels. The vessels will travel along series of transects at slow speeds while observers on the vessels identify the number and species of animals. Ecological sampling and marine mammal surveys will also be conducted from fixed wing aircraft as part of the mandatory marine mammal monitoring programs associated with seismic surveys and exploration drilling. Various types of buoys will likely be deployed in the Chukchi Sea for data collection.

Onshore Environmental Studies

Various types of environmental studies will likely also occur during the life of these regulations. These could include, but may not be limited to, hydrology studies; habitat assessments; fish and wildlife surveys; and archaeological resource surveys. These studies will generally be conducted by small teams of scientists based in Chukchi Sea communities and travelling to study sites by helicopter. Most surveys will be conducted on foot or from the air. Small boats may be used for hydrology studies, fish surveys, and other studies in aquatic environments.

During the previous 5-year time period of the regulations (2008–2013), a total of six environmental studies were conducted, with one to two conducted per year. Based upon information provided by the petitioners, we estimate that as many as two environmental studies may be conducted in any given year during the 5-year timeframe of these regulations (2013 to 2018).

Additional Onshore Activities

Additional onshore activities may occur as well. The North Slope Borough (NSB) operates the Barrow Gas Fields located south and east of the city of Barrow. The Barrow Gas Fields include the Walakpa, South, and East Gas Fields; of these, the Walakpa Gas Field and a portion of the South Gas Field are located within the boundaries of the Chukchi Sea geographical region while the East Barrow Gas Field is currently regulated under the ITRs for the Beaufort Sea and therefore not discussed here. The Walakpa Gas Field operation is currently accessed by helicopter and/or a rolligon trail. The South Gas Field is accessible by gravel road or dirt trail depending on the individual well. Access to this field during the winter will require ice road construction. Ice/snow road access and ice pads are proposed where needed. In 2007, ConocoPhillips conducted an exploration program south of Barrow near the Walakpa Gas Field. The NSB conducted drilling activities in 2007, including drilling new gas wells, and plugged and abandoned depleted wells in the Barrow Gas Fields. During the 5-year timeframe of these regulations (2013 to 2018), we expect the NSB to maintain an active presence in the gas fields with the potential for additional maintenance of the fields.

Biological Information

Pacific Walrus (Odobenus rosmarus divergens)

The Pacific walrus is the largest pinniped species (aquatic carnivorous mammals with all four limbs modified into flippers) in the Arctic. Walruses are readily distinguished from other Arctic pinnipeds by their enlarged upper canine teeth, which form prominent tusks. Males, which have relatively larger tusks than females, also tend to have broader skulls (Fay 1982).

Two modern subspecies of walruses are generally recognized (Wozencraft 2005, p. 525; Integrated Taxonomic Information System, 2010): The Atlantic walrus (*O. r. rosmarus*), which ranges from the central Canadian Arctic eastward to the Kara Sea (Reeves 1978), and the Pacific walrus (*O. r. divergens*), which ranges across the Bering and Chukchi seas (Fay 1982). The small, geographically isolated population of walruses in the Laptev Sea (Heptner *et al.* 1976; Vishnevskaia and Bychkov

1990; Andersen *et al.* 1998; Wozencraft 2005; Jefferson *et al.* 2008), which was previously known as the Laptev walrus (Lindqvist *et al.* 2009), is now considered part of the Pacific walrus population. Atlantic and Pacific walruses are genetically and morphologically distinct from each other (Cronin *et al.* 1994), likely because of range fragmentation and differentiation during glacial phases of extensive Arctic sea ice cover (Harington 2008).

Stock Definition, Range, and Abundance

Pacific walruses are represented by a single stock of animals that inhabit the shallow continental shelf waters of the Bering and Chukchi seas (Sease and Chapman 1988). Though some heterogeneity in the populations has been documented by Jay *et al.* (2008) from differences in the ratio of trace elements in the teeth, Scribner *et al.* (1997) found no difference in mitochondrial or nuclear DNA among Pacific walruses sampled from different breeding areas. The population ranges across the international boundaries of the United States and Russian Federation, and both nations share common interests with respect to the conservation and management of this species. Pacific walruses are identified and managed in the United States and the Russian Federation as a single population (Service 2010).

Pacific walruses range across the continental shelf waters of the northern Bering Sea and Chukchi Sea, relying principally on broken pack ice habitat to access feeding areas of high benthic productivity (Fay 1982). Pacific walruses migrate up to 1,500 km (932 mi) between summer foraging areas in the Arctic (primarily the offshore continental shelf of the Chukchi Sea) and highly productive, seasonally ice covered waters in the sub-Arctic (northern Bering Sea) in winter. Although many adult male Pacific walruses remain in the Bering Sea during the ice-free season, where they forage from coastal haulouts, most of the population migrates north in summer and south in winter following seasonal patterns of ice advance and retreat. Walruses are rarely spotted south of the Aleutian archipelago; however, migrant animals (mostly males) are occasionally reported in the North Pacific. Pacific walruses are presently identified and managed as a single panmictic population (Service 2010, unpublished data).

Fossil evidence suggests that walruses occurred in the northwest Pacific during the last glacial maximum (20,000 YBP) with specimens recovered as far south as northern California (Gingras *et al.* 2007; Harrington 2008). More recently, commercial harvest records indicate that Pacific walruses were hunted along the southern coast of the Russian Federation in the Sea of Okhotsk and near Unimak Pass (Aleutian Islands) and the Shumigan Islands (Alaska Peninsula) of Alaska during the 17th Century (Elliott 1882).

Pacific walruses are highly mobile, and their distribution varies markedly in response to seasonal and annual variations in sea ice cover. During the January to March breeding season, walruses congregate in the Bering Sea pack ice in areas where open leads (fractures in sea ice caused by wind drift or ocean currents), polynyas (enclosed areas of unfrozen water surrounded by ice) or thin ice allow access to water (Fay 1982; Fay *et al.* 1984). The specific location of winter breeding aggregations varies annually depending upon the distribution and extent of ice. Breeding aggregations have been reported southwest of St. Lawrence Island, Alaska; south of Nunivak Island, Alaska; and south of the Chukotka Peninsula in the Gulf of Anadyr, Russian Federation (Fay 1982; Mymrin *et al.* 1990; Figure 1 in Garlich-Miller *et al.* 2011a).

In spring, as the Bering Sea pack ice deteriorates, most of the population migrates northward through the Bering Strait to summer feeding areas over the continental shelf in the Chukchi Sea. However, several thousand animals, primarily adult males, remain in the Bering Sea during the summer months, foraging from coastal haulouts in the Gulf of Anadyr, Russian Federation, and in Bristol Bay, Alaska (Figure 1 in Garlich-Miller *et al.* 2011a).

Summer distributions (both males and females) in the Chukchi Sea vary annually, depending upon the extent of sea ice. When broken sea ice is abundant, walruses are typically found in patchy aggregations over continental shelf waters. Individual groups may range from fewer than 10 to more than 1,000 animals (Gilbert 1999; Ray *et al.* 2006). Summer concentrations have been reported in loose pack ice off the northwestern coast of Alaska, between Icy Cape and Point Barrow, and along the coast of Chukotka, Russian Federation, and Wrangel Island (Fay 1982; Gilbert *et al.* 1992; Belikov *et al.* 1996). In years of low ice concentrations in the Chukchi Sea, some animals range east of Point Barrow into the Beaufort Sea; walruses have also been observed in the Eastern Siberian Sea in late summer (Fay 1982; Belikov *et al.* 1996). The pack ice of the Chukchi Sea usually reaches its minimum extent in September. In years when the sea ice retreats north beyond the continental shelf, walruses congregate in large numbers (up to several tens of thousands of animals in some locations) at terrestrial haulouts on Wrangel Island and other sites along the northern coast of the Chukotka Peninsula, Russian Federation, and northwestern Alaska (Fay 1982; Belikov *et al.* 1996; Kochnev 2004; Ovsyanikov *et al.* 2007; Kavry *et al.* 2008; MacCracken 2012).

In late September and October, walruses that summered in the Chukchi Sea typically begin moving south in advance of the developing sea ice. Satellite telemetry data indicate that male walruses that summered at coastal haulouts in the Bering Sea also begin to move northward towards winter breeding areas in November (Jay and Hills 2005). The male walruses' northward movement appears to be driven primarily by the presence of females at that time of year (Freitas *et al.* 2009).

Distribution in the Chukchi Sea

During the summer months, walruses are widely distributed across the shallow continental shelf waters of the Chukchi Sea. Significant summer concentrations include near Wrangel and Herald Islands in Russian waters and at Hanna Shoal (northwest of Point Barrow) in U.S. waters (Jay *et al.* 2012). As the ice edge advances southward in the fall, walruses reverse their migration and re-group on the Bering Sea pack ice.

The distribution of walruses in the eastern Chukchi Sea where exploration activities will occur is influenced primarily by the distribution and extent of seasonal pack ice. In June and July, scattered groups of walruses are typically found in loose pack ice habitats between Icy Cape and Point Barrow (Fay 1982; Gilbert *et al.* 1992). Recent telemetry studies investigating foraging patterns in the eastern Chukchi Sea suggest that many walruses focus foraging efforts near Hanna Shoal, northwest of Point Barrow (Jay *et al.* 2012). In August and September, concentrations of animals tend to be in areas of unconsolidated pack ice, usually within 100 km of the leading edge of the ice pack (Gilbert 1999). Individual groups occupying unconsolidated pack ice typically range from fewer than 10 to more than 1,000 animals. (Gilbert 1999; Ray *et al.* 2006). In August and September, the edge of the pack ice generally retreats northward to about 71° N latitude; however in light ice years, the edge can retreat north beyond the continental shelf (Douglas 2010). Sea ice normally reaches its minimum (northern) extent sometime in September, and ice begins

to reform rapidly in October and November. Walruses typically migrate out of the eastern Chukchi Sea in October in advance of the developing sea ice (Fay 1982; Jay *et al.* 2012).

Hanna Shoal Walrus Use Area

Hanna Shoal is a region of the northeastern Chukchi Sea of shallow water and moderate to high benthic productivity (Grebmeier *et al.* 2006; Dunton 2013) that is important to many species of wildlife, including the Pacific walrus. Walruses forage in the region from June to October, at times reaching numbers of tens of thousands of animals (Brueggeman *et al.* 1990, 1991; MacCracken 2012; Jay *et al.* 2012). The Hanna Shoal region has been defined variably in different technical and scientific documents, based on different attributes such as: bathymetry, currents, sea ice dynamics, benthic productivity, animal use patterns, and other administrative considerations. For example, the Audubon Society (Smith 2011) defined Hanna Shoal based on bathymetry, delineating an area of approximately 5,700 km^2 (2,200 mi^2). The National Marine Fisheries Service (NMFS) (2013) defined Hanna Shoal as an area of high biological productivity and a feeding area for various marine mammals, including bearded seals (*Erignathus barbatus*) and ringed seals (*Pusa hispida*). Their maps delineate an area of approximately 7,876 km^2 (3,041 mi^2). The BOEM Environmental Studies Program reflects both a Hanna Shoal Regional Study Area and a Hanna Shoal Core Study Area of about 720,000 km^2 (278,000 mi^2) and 150,000 km^2 (58,000 mi^2), respectively (BOEM 2013). For the purposes of these ITRs, the Service is delineating the Hanna Shoal region by use patterns of Pacific walruses, hereinafter referred to as the Hanna Shoal Walrus Use Area (HSWUA), and further described below.

The Hanna Shoal region has long been recognized as a critical foraging area for the Pacific walrus in summer and fall (Brueggeman *et al.* 1990, 1991; MacCracken 2012; Jay *et al.* 2012), and the Service delineated the HSWUA using walrus foraging and occupancy utilization distributions (UDs) from Jay *et al.* (2012) for the months of June through September (Figure 2; see Final Regulation Promulgation section). Jay *et al.* (2012) used walrus satellite telemetry from the Chukchi Sea to delineate UDs of walrus foraging and occupancy during summer and fall from 2008 to 2011. The UDs described in Jay *et al.* (2012) represent the probability of animals using an area during the time specified. Utilization distributions are a commonly accepted way to delineate areas of concentrated use by a species and the 50 percent UD is often identified as the core use area or area of most concentrated use in many habitat use studies (Samuel *et al.* 1985; Powell 2000; Laver and Kelley 2008). We consider the combined 50 percent foraging and occupancy UDs from Jay *et al.* (2012) at Hanna Shoal from June to September to represent the core use area during the time of most concentrated use by walruses, and, therefore, the most appropriate way to delineate the Hanna Shoal region as it pertains to walruses.

To delineate the HSWUA, we overlaid the 50 percent UDs for both foraging and occupancy in Jay *et al.* (2012) in the Hanna Shoal area, as defined bathymetrically by Smith (2011), for the months of June through September. The combined area of those 50 percent UDs produced two adjacent polygons, one on the north slope of the bathymetrically defined shoal and one on the south slope of the bathymetrically defined shoal. We recognize that animals using the areas delineated by those two polygons would be frequently crossing back and forth between those areas and, therefore, joined the two polygons at the closest point on the west and east ends. The final HSWUA totals approximately 24,600 km^2 (9,500 mi^2) (Figure 2; see Final Regulation Promulgation section) and can be viewed at: *http://alaska.fws.gov/fisheries/mmm/pdf/itr_fr2013_pb_pw.pdf.*

We believe that it is critical to minimize disturbance to walruses in this area of highly concentrated use during July through September. Due to the large numbers of walruses that could be encountered in the HSWUA from July through September, the Service has determined that additional mitigation measures, such as seasonal restrictions, reduced vessel traffic, or rerouting vessels, may be necessary for activities within the HSWUA to minimize potential disturbance and ensure consistency with the MMPA mandates that only small numbers of walruses be affected with a negligible impact on the stock. On a case-by-case basis, as individual LOA applications are received, we will examine the proposed activities in light of the boundaries of the HSWUA, the nature and timing of the proposed activities, and other available information at the time. If the Service determines that the proposed activity is likely to negatively impact more than small numbers of walruses, we will consider whether additional mitigation and monitoring measures could reduce any potential impacts to meet the small numbers and negligible impact standards. The Service will make those determinations on a case-by-case basis.

Population Status

The size of the Pacific walrus population has never been known with certainty. Based on large sustained harvests in the 18th and 19th centuries, Fay (1982) speculated that the pre-exploitation population was represented by a minimum of 200,000 animals. Since that time, population size is believed to have fluctuated in response to varying levels of human exploitation. Large scale commercial harvests are believed to have reduced the population to 50,000 to 100,000 animals by the mid-1950s (Fay *et al.* 1997). The population apparently increased rapidly in size during the 1960s and 1970s, in response to harvest regulations that limited the take of females (Fay *et al.* 1989). Between 1975 and 1990, visual aerial surveys jointly conducted by the United States and Soviet Union at 5-year intervals produced population estimates ranging from 201,039 to 246,360 (Table 1). Efforts to survey the Pacific walrus population were suspended by both countries after 1990, due to unresolved problems with survey methods that produced population estimates with unknown bias and unknown, but presumably large, variances that severely limited their utility (Speckman *et al.* 2012).

In 2006, a joint United States-Russian Federation survey was conducted in the pack ice of the Bering Sea, using thermal imaging systems to detect walruses hauled out on sea ice and satellite transmitters to account for walruses in the water (Speckman *et al.* 2012). The number of walruses within the surveyed area was estimated at 129,000, with a 95 percent confidence interval of 55,000 to 507,000 individuals. This is a conservative minimum estimate, as weather conditions forced termination of the survey before much of the southwest Bering Sea was surveyed; animals were observed in that region as the surveyors returned to Anchorage, Alaska. Table 1 provides a summary of survey results.

TABLE 1—ESTIMATES OF PACIFIC WALRUS POPULATION SIZE, 1975 TO 2006

Year	Population size [a] (95% confidence interval)	Reference
1975	214,687 (–20,000 to 480,000) [b]	Udevitz *et al.* 2001.
1980	246,360 (–20,000 to 540,000)	Johnson *et al.* 1982; Fedoseev 1984.
1985	242,366 (–20,000 to 510,000)	Udevitz *et al.* 2001.
1990	201,039 (–19,000 to 460,000)	Gilbert *et al.* 1992.
2006	129,000 (55,000 to 507,000)	Speckman *et al.* 2011.

[a] Due to differences in methods, comparisons of estimates across years (population trend) are subject to several caveats and not reliable.
[b] 95 percent confidence intervals for 1975 to 1990 are from Fig. 1 in Hills and Gilbert (1994).

These estimates suggest that the walrus population has declined; however, discrepancies among the survey methods and large confidence intervals that in some cases overlap zero do not support such a definitive conclusion. Resource managers in the Russian Federation have concluded that the population has declined and have reduced harvest quotas in recent years accordingly (Kochnev 2004; Kochnev 2005; Kochnev 2010, pers. comm.), based in part on the lower abundance estimate generated from the 2006 survey. However, past survey results are not directly comparable due to differences in survey methods, timing of surveys, segments of the population surveyed, and incomplete coverage of areas where walruses may have been present (Fay *et al.* 1997); thus, these results do not provide a basis for determining trend in population size (Hills and Gilbert 1994; Gilbert 1999). Whether prior estimates are biased low or high is unknown, because of problems with detecting individual animals on ice or land, and in open water, and difficulties counting animals in large, dense groups (Speckman *et al.* 2011). In addition, no survey has ever been completed within a time frame that could account for the redistribution of individuals (leading to double counting or undercounting), or before weather conditions either delayed the effort or completely terminated the survey before the entire area of potentially occupied habitat had been covered (Speckman *et al.* 2011). Due to these problems, as well as seasonal differences among surveys (fall or spring) and despite technological advancements that correct for some problems, we do not believe the survey results provide a reliable basis for estimating a population trend.

Changes in the walrus population have also been investigated by examining changes in biological parameters over time. Based on evidence of changes in abundance, distributions, condition indices, pregnancy rates, and minimum breeding age, Fay *et al.* (1989) and Fay *et al.* (1997) concluded that the Pacific walrus population increased greatly in size during the 1960s and 1970s, and postulated that the population was near, or had exceeded, the carrying capacity (K) of its environment by the early 1980s. We will expect the population to decline if K is exceeded. In addition, harvests increased in the 1980s. Changes in the size, composition, and productivity of the sampled walruses harvested in the Bering Strait region of Alaska over this time frame are consistent with this hypothesis (Garlich-Miller *et al.* 2006; MacCracken 2012). Harvest levels declined sharply in the early 1990s, and increased reproductive rates and earlier maturation in females occurred, suggesting that density dependent regulatory mechanisms had been relaxed and the population was likely below K (Garlich-Miller *et al.* 2006; MacCracken 2012). However, Garlich-Miller *et al.* (2006) also noted that there are no data concerning the trend in abundance of the walrus population or the status of its prey to verify this hypothesis, and that whether density dependent changes in life-history parameters might have been mediated by changes in population abundance or changes in the carrying capacity of the environment is unknown.

Habitat

The Pacific walrus is an ice-dependent species that relies on sea ice for many aspects of its life history. Unlike other pinnipeds, walruses are not adapted for a pelagic existence and must haul out on ice or land regularly. Floating pack ice serves as a substrate for resting between feeding dives (Ray *et al.* 2006), breeding behavior (Fay *et al.* 1984), giving birth (Fay 1982), and nursing and care of young (Kelly 2001). Sea ice provides access to offshore feeding areas over the continental shelf of the Bering and Chukchi Seas, passive transportation to new feeding areas (Richard 1990; Ray *et al.* 2006), and isolation from terrestrial predators (Richard 1990; Kochnev 2004; Ovsyanikov *et al.* 2007). Sea ice provides an extensive substrate upon which the risk of predation and hunting is greatly reduced (Kelly 2001; Fay 1982).

Sea ice in the Northern Hemisphere is comprised of first year sea ice that formed in the most recent autumn/winter period, and multi-year ice that has survived at least one summer melt season. Sea ice habitats for walruses include openings or leads that provide access to the water and to food resources. Walruses generally do not use multi-year ice or highly compacted first year ice in which there is an absence of persistent leads or polynyas (Richard 1990). Expansive areas of heavy ice cover are thought to play a restrictive role in walrus distributions across the Arctic and serve as a barrier to the mixing of populations (Fay 1982; Dyke *et al.* 1999; Harington 2008). Walruses generally do not occur farther south than the maximum extent of the winter pack ice, possibly due to their reliance on sea ice for breeding and rearing young (Fay *et al.* 1984) and isolation from terrestrial predators (Kochnev 2004; Ovsyanikov *et al.* 2007), or because of the higher densities of benthic invertebrates in northern waters (Grebmeier *et al.* 2006a).

Walruses may utilize ice that is greater than 20 cm (~8 in), but generally require ice thicknesses of 50 cm (~20 in) or more to support their weight, and are not found in areas of extensive, unbroken ice (Fay 1982; Richard 1990). Thus, in winter they concentrate in areas of broken pack ice associated with divergent ice flow or along the margins of persistent polynyas (Burns *et al.* 1981; Fay *et al.* 1984; Richard 1990) in areas with abundant food resources (Ray *et al.* 2006). Females with young generally spend the summer months in pack ice habitats of the Chukchi Sea. Some authors have suggested that the size and topography of individual ice floes are important features in the selection of ice haulouts, noting that some animals have been observed returning to the same ice floe between feeding bouts (Ray *et al.* 2006). Conversely, walruses can and will exploit a broad range of ice types and

ice concentrations in order to stay in preferred foraging or breeding areas (Freitas *et al.* 2009; Jay *et al.* 2010; Ray *et al.* 2010). Walruses tend to make shorter foraging excursions when they are using sea ice rather than land haulouts (Udevitz *et al.* 2009), suggesting that it is more energetically efficient for them to haulout on ice than forage from shore. Fay (1982) noted that several authors reported that when walruses had the choice of ice or land for a resting place, ice was always selected. However, walrus occupancy of an area can be somewhat independent of ice conditions. Many walruses will stay over productive feeding areas even to the point when the ice completely melts out. It appears that adult females and younger animals can remain at sea for a week or two before coming to shore to rest.

When suitable sea ice is not available, walruses haul out on land to rest. A wide variety of substrates, ranging from sand to boulders, are used. Isolated islands, points, spits, and headlands are occupied most frequently. The primary consideration for a terrestrial haulout site appears to be isolation from disturbances and predators, although social factors, learned behavior, protection from strong winds and surf, and proximity to food resources also likely influence the choice of terrestrial haulout sites (Richard 1990). Walruses tend to use established haulout sites repeatedly and exhibit some degree of fidelity to these sites (Jay and Hills 2005), although the use of coastal haulouts appears to fluctuate over time, possibly due to localized prey depletion (Garlich-Miller and Jay 2000). Human disturbance is also thought to influence the choice of haulout sites; many historic haulouts in the Bering Sea were abandoned in the early 1900s when the Pacific walrus population was subjected to high levels of exploitation (Fay 1982; Fay *et al.* 1984).

Adult male walruses use land-based haulouts more than females or young, and consequently, have a greater geographical distribution through the ice-free season. Many adult males remain in the Bering Sea throughout the ice-free season, making foraging trips from coastal haulouts in Bristol Bay, Alaska, and the Gulf of Anadyr, Russian Federation (Figure 1 in Garlich-Miller *et al.* 2011a), while females and juvenile animals generally stay with the drifting ice pack throughout the year (Fay 1982). Females with dependent young may prefer sea ice habitats because coastal haulouts pose greater risk from trampling injuries and predation (Fay and Kelly 1980; Ovsyanikov *et al.* 1994; Kochnev 2004; Ovsyanikov *et al.* 2007; Kavry *et al.* 2008; Mulcahy *et al.* 2009). Females may also prefer sea ice habitats because they may have difficulty feeding while caring for a young calf that has limited swimming range (Cooper *et al.* 2006; Jay and Fischbach 2008).

The numbers of male walruses using coastal haulouts in the Bering Sea during the summer months, and the relative uses of different coastal haulout sites in the Bering Sea, have varied over the past century. Harvest records indicate that walrus herds were once common at coastal haulouts along the Alaska Peninsula and the islands of northern Bristol Bay (Fay *et al.* 1984). By the early 1950s, most of the traditional haulout areas in the southern Bering Sea had been abandoned, presumably due to hunting pressure. During the 1950s and 1960s, Round Island was the only regularly used haulout in Bristol Bay, Alaska. In 1960, the State of Alaska established the Walrus Islands State Game Sanctuary, which closed Round Island to hunting. Peak counts of walruses at Round Island increased from 1,000 to 2,000 animals in the late 1950s (Frost *et al.* 1983) to more than 10,000 animals in the early 1980s (Sell and Weiss 2010), but subsequently declined to 2,000 to 5,000 over the past decade (Sell and Weiss 2010). General observations indicate that declining walrus counts at Round Island may, in part, reflect a redistribution of animals to other coastal sites in the Bristol Bay region. For example, walruses have been observed increasingly regularly at the Cape Seniavin haulout on the Alaska Peninsula since the 1970s, and at Cape Pierce and Cape Newenham in northwest Bristol Bay since the early 1980s (Jay and Hills 2005; Winfree 2010; Figure 1 in Garlich-Miller *et al.* 2011a), and more recently at Hagemeister Island.

Traditional male summer haulouts along the Bering Sea coast of the Russian Federation include sites along the Kamchatka Peninsula, the Gulf of Anadyr (most notably Rudder and Meechkin spits), and Arakamchechen Island (Garlich-Miller and Jay 2000; Figure 1 in Garlich-Miller *et al.* 2011a). Walruses have not occupied several of the southernmost haulouts along the coast of Kamchatka in recent years, and the number of animals in the Gulf of Anadyr has also declined in recent years (Kochnev 2005). Factors influencing abundance at Bering Sea haulouts are poorly understood, but may include changes in prey densities near the haulouts, changes in population size, disturbance levels, and changing seasonal distributions (Jay and Hills 2005) (presumably mediated by sea ice coverage or temperature).

Historically, coastal haulouts along the Arctic (Chukchi Sea) coast have been used less consistently during the summer months than those in the Bering Sea because of the presence of pack ice for much of the year in the Chukchi Sea. Since the mid-1990s, reductions of summer sea ice coincided with a marked increase in the use of coastal haulouts along the Chukchi Sea coast of the Russian Federation during the summer months (Kochnev 2004; Kavry *et al.* 2008). Large, mixed (composed of various age and sex groups) herds of walruses, up to several tens of thousands of animals, began to use coastal haulouts on Wrangel Island, Russian Federation, in the early 1990s, and several coastal haulouts along the northern Chukotka coastline of the Russian Federation have emerged in recent years, likely as a result of reductions in summer sea ice in the Chukchi Sea (Kochnev 2004; Ovsyanikov *et al.* 2007; Kavry *et al.* 2008; Figure 1 in Garlich-Miller *et al.* 2011a).

In 2007, 2009, 2010, and 2011, walruses were also observed hauling out in large numbers with mixed sex and age groups along the Chukchi Sea coast of Alaska in late August, September, and October (Thomas *et al.* 2009; Service 2010, unpublished data; Garlich-Miller *et al.* 2011b; MacCracken 2012). Monitoring studies conducted in association with oil and gas exploration suggest that the use of coastal haulouts along the Arctic coast of Alaska during the summer months is dependent upon the availability of sea ice. For example, in 2006 and 2008, walruses foraging off the Chukchi Sea coast of Alaska remained with the ice pack over the continental shelf during the months of August, September, and October. However in 2007 and 2009, the pack ice retreated beyond the continental shelf and large numbers of walruses hauled out on land at several locations between Point Barrow and Cape Lisburne, Alaska (Ireland *et al.* 2009; Thomas *et al.* 2009; Service 2010, unpublished data; Figure 1 in Garlich-Miller *et al.* 2011a), and in 2010 and 2011, at least 20,000 to 30,000 walruses were observed hauled out approximately 4.8 km (3 mi) north of the Native Village of Point Lay, Alaska (Garlich-Miller *et al.* 2011b).

Transitory coastal haulouts have also been reported in late fall (October to November) along the southern Chukchi Sea coast, coinciding with the southern migration. Mixed herds of walruses frequently come to shore to rest for a few days to weeks along the coast before continuing on their migration to the

Bering Sea. Cape Lisburne, Alaska, and Capes Serdtse-Kamen' and Dezhnev, Russian Federation, are the most consistently used haulouts in the Chukchi Sea at this time of year (Garlich-Miller and Jay 2000). Large mixed herds of walruses have also been reported in late fall and early winter at coastal haulouts in the northern Bering Sea at the Punuk Islands and Saint Lawrence Island, Alaska; Big Diomede Island, Russian Federation; and King Island, Alaska, prior to the formation of sea ice in offshore breeding and feeding areas (Fay and Kelly 1980; Garlich-Miller and Jay 2000; Figure 1 in Garlich-Miller *et al.* 2011a).

Life History

Walruses are long-lived animals with low rates of reproduction, much lower than other pinniped species. Walruses may live 35 to 40 years and some may remain reproductively active until relatively late in life (Garlich-Miller *et al.* 2006). Females give birth to one calf every 2 or more years. Breeding occurs between January and March in the pack ice of the Bering Sea. Calves are usually born in late April or May the following year during the northward migration from the Bering Sea to the Chukchi Sea. Calving areas in the Chukchi Sea extend from the Bering Strait to latitude 70°N (Fay *et al.* 1984). At birth, walrus calves weigh approximately 65 kg (143 pounds [lb]) and are about 113 cm (44.5 in) long (Fay 1982). Calves are capable of entering the water shortly after birth, but tend to haulout frequently, until their swimming ability and blubber layer are well developed. Females tend newborn calves closely and accompany their mother from birth until weaned after 2 years or more. Cows brood neonates to aid in their thermoregulation (Fay and Ray 1968), and carry them on their back or under their flipper while in the water (Gehnrich 1984). Females with newborns often join to form large ''nursery herds'' (Burns 1970). Summer distribution of females and young walruses is related to the movements of the pack ice relative to feeding areas.

After the first 7 years of life, the growth rate of female walruses declines rapidly, and they reach a maximum body size by approximately 10 years of age. Females reach sexual maturity at 4 to 9 years of age. Adult females can reach lengths of up to 3 m (9.8 ft) and weigh up to 1,100 kg (2,425 lb). Male walruses tend to grow faster and for a longer period than females. Males become fertile at 5 to 7 years of age; however, they are usually unable to compete for mates until they reach full adult body size at 15 to 16 years of age. Adult males can reach lengths of 3.5 m (11.5 ft) and can weigh more than 2,000 kg (4,409 lb) (Fay 1982).

Behavior

Walruses are social and gregarious animals. They tend to travel in groups and haul out of the water to rest on ice or land in densely packed groups. On land or ice, in any season, walruses tend to lie in close physical contact with each other. Young animals often lie on top of adults. Group size can range from a few individuals up to several thousand animals (Gilbert 1999; Kastelein 2002; Jefferson *et al.* 2008). At any time of the year, when groups are disturbed, stampedes from a haulout can result in injuries and mortalities. Calves and young animals are particularly vulnerable to trampling injuries (Fay 1980; Fay and Kelly 1980). The reaction of walruses to disturbance ranges from no reaction to escape into the water, depending on the circumstances (Fay *et al.* 1984). Many factors play into the severity of the response, including the age and sex of the animals, the size and location of the group (on ice, in water, Fay *et al.* 1984). Females with calves appear to be most sensitive to disturbance, and animals on shore are more sensitive than those on ice (Fay *et al.* 1984). A fright response caused by disturbance can cause stampedes on a haulout, resulting in injuries and mortalities (Fay and Kelly 1980).

Mating occurs primarily in January and February in broken pack ice habitat in the Bering Sea. Breeding bulls follow herds of females and compete for access to groups of females hauled out onto sea ice. Males perform visual and acoustical displays in the water to attract females and defend a breeding territory. Sub-dominant males remain on the periphery of these aggregations and apparently do not display. Intruders into display areas are met with threat displays and physical attacks. Individual females leave the resting herd to join a male in the water, where copulation occurs (Fay *et al.* 1984; Sjare and Stirling 1996).

The social bond between the mother and calf is very strong, and it is unusual for a cow to become separated from her calf (Fay 1982). The calf normally remains with its mother for at least 2 years, sometimes longer, if not supplanted by a new calf (Fay 1982). After separation from their mother, young females tend to remain with groups of adult females, whereas young males gradually separate from the females and begin to associate with groups of other males. Walruses appear to base their individual social status on a combination of body size, tusk size, and aggressiveness. Individuals do not necessarily associate with the same group of animals and must continually reaffirm their social status in each new aggregation (Fay 1982; NAMMCO 2004).

Walruses produce a variety of sounds (barks, knocks, grunts, rasps, clicks, whistles, contact calls, etc.; Miller 1985; Stirling *et al.* 1987), which range in frequency from 0.1 to 4,000 hertz [Hz] (Miller 1985; Richardson *et al.* 1995). Airborne vocalizations accompany nearly every social interaction that occurs on land or ice (Miller 1985; Charrier *et al.* 2011) and facilitate kin recognition, male breeding displays, recognition of conspecifics, and female mate choice (Insley *et al.* 2003; Charrier *et al.* 2011). Miller (1985) indicated that barks and other calls were used to promote group cohesion and prompted herd members to attend to young distressed animals. Walruses also vocalize extensively while underwater, which has been used to track movements, study behavior, and infer relative abundance (Stirling *et al.* 1983; Hannay *et al.* 2012, Mouy *et al.* 2012). The purposes of underwater vocalizations are not explicitly known but are associated with breeding (Ray and Watkins 1975; Stirling *et al.* 1987; Sjare *et al.* 2003), swimming, and diving (Hannay *et al.* 2012). Stirling *et al.* (1987) suggested that variation among individuals in stereotyped underwater calls may be used to identify individuals. Mouy *et al.* (2012) opined that knocks made while diving may be used to locate the bottom and identify bottom substrates associated with prey. Underwater vocalizations may also be used to communicate with other walruses.

Because of walrus grouping behavior, all vocal communications occur within a short distance (Miller 1985). Walruses' underwater vocalizations can be detected for only a few kilometers (Mouy *et al.* 2012) and likely do not act as long distance communication.

Prey

Walruses consume mostly benthic (region at the bottom of a body of water) invertebrates and are highly adapted to obtain bivalves (Fay 1982; Bowen and Siniff 1999; Born *et al.* 2003; Dehn *et al.* 2007; Boveng *et al.* 2008; Sheffield and Grebmeier 2009). Fish and other vertebrates have occasionally been found in their stomachs (Fay 1982; Sheffield and Grebmeier 2009). Walruses root in the bottom sediment with their muzzles and use their whiskers to locate prey items. They use their fore flippers, nose, and jets of water to extract prey buried up to 32 cm

(12.6 in) (Fay 1982; Oliver *et al.* 1983; Kastelein 2002; Levermann *et al.* 2003). The foraging behavior of walruses is thought to have a major impact on benthic communities in the Bering and Chukchi Seas (Oliver *et al.* 1983; Klaus *et al.* 1990). Ray *et al.* (2006) estimate that walruses consume approximately 3 million metric tons (3,307 tons) of benthic biomass annually, and that the area affected by walruses foraging is in the order of thousands of sq km (thousands of sq mi) annually. Consequently, walruses play a major role in benthic ecosystem structure and function, which Ray *et al.* (2006) suggested increased nutrient flux and productivity.

The earliest studies of food habits were based on examination of stomachs from walruses killed by hunters. These reports indicated that walruses were primarily feeding on bivalves (clams), and that non-bivalve prey was only incidentally ingested (Fay 1982; Sheffield *et al.* 2001). However, these early studies did not take into account the differential rate of digestion of prey items (Sheffield *et al.* 2001). Additional research indicates that stomach contents include over 100 taxa of benthic invertebrates from all major phyla (Fay 1982; Sheffield and Grebmeier 2009), and while bivalves remain the primary component, walruses are not adapted to a diet solely of clams. Other prey items have similar energetic benefits (Wacasey and Atkinson 1987). Based on analysis of the contents from fresh stomachs of Pacific walruses collected between 1975 and 1985 in the Bering Sea and Chukchi Sea, prey consumption likely reflects benthic invertebrate composition (Sheffield and Grebmeier 2009). Of the large number of different types of prey, statistically significant differences between males and females from the Bering Sea were found in the occurrence of only two prey items, and there were no statistically significant differences in results for males and females from the Chukchi Sea (Sheffield and Grebmeier 2009). Although these data are for Pacific walruses stomachs collected 25 to 35 years ago, we have no reason to believe there has been a change in the general pattern of prey use described here.

Walruses typically swallow invertebrates without shells in their entirety (Fay 1982). Walruses remove the soft parts of mollusks from their shells by suction, and discard the shells (Fay 1982). Born *et al.* (2003) reported that Atlantic walruses consumed an average of 53.2 bivalves (range 34 to 89) per dive. Based on caloric need and observations of captive walruses, walruses require approximately 29 to 74 kg (64 to 174 lbs) of food per day (Fay 1982). Adult males forage little during the breeding period (Fay 1982; Ray *et al.* 2006), while lactating females may eat two to three times that of non-pregnant, non-lactating females (Fay 1982). Calves up to 1 year of age depend primarily on their mother's milk (Fay 1982) and are gradually weaned in their second year (Fisher and Stewart 1997).

Although walruses are capable of diving to depths of more than 250 m (820 ft) (Born *et al.*), they usually forage in waters of 80 m (262 ft) or less (Fay and Burns 1988, Born *et al.* 2003; Kovacs and Lydersen 2008), presumably because of higher productivity of their benthic foods in shallow waters (Fay and Burns 1988; Carey 1991; Jay *et al.* 2001; Grebmeier *et al.* 2006b; Grebmeier *et al.* 2006a). Walruses make foraging trips from land or ice haulouts that range from a few hours up to several days and up to 100 km (60 mi) (Jay *et al.* 2001; Born *et al.* 2003; Ray *et al.* 2006; Udevitz *et al.* 2009). Walruses tend to make shorter and more frequent foraging trips when sea ice is used as a foraging platform compared to terrestrial haulouts (Udevitz *et al.* 2009). Satellite telemetry data for walruses in the Bering Sea in April of 2004, 2005, and 2006 showed they spent an average of 46 hours in the water between resting bouts on ice, which averaged 9 hours (Udevitz *et al.* 2009). Because females and young travel with the retreating pack ice in the spring and summer, they are passively transported northward over feeding grounds across the continental shelves of the Bering and Chukchi Seas. Male walruses appear to have greater endurance than females, with foraging excursions from land haulouts that can last up to 142 hours (about 6 days) (Jay *et al.* 2001).

Mortality

Polar bears are known to prey on walrus calves, and killer whales (*Orcinus orca*) have been known to take all age classes of walruses. Predation levels are thought to be highest near terrestrial haulout sites where large aggregations of walruses can be found; however, few observations exist for offshore environs. Pacific walruses have been hunted by coastal Natives in Alaska and Chukotka for thousands of years. Exploitation of the Pacific walrus population by Europeans has also occurred in varying degrees since the late 17th century. Currently only Native Alaskans and Chukotkans can hunt Pacific walruses to meet subsistence needs. The Service, in partnership with the Eskimo Walrus Commission (EWC) and the Association of Traditional Marine Mammal Hunters of Chukotka, administered subsistence harvest monitoring programs in Alaska and Chukotka between 2000 to 2005. Harvests from 2006 to 2010 averaged 4,854 walruses per year (Service, unpubl. data). These mortality estimates include corrections for under-reported harvest and struck and lost animals.

Intra-specific trauma is also a known source of injury and mortality. Disturbance events can cause walruses to stampede into the water and have been known to result in hundreds to thousands of injuries and mortalities. The risk of stampede-related injuries increases with the number of animals hauled out. Calves and young animals at the perimeter of these herds are particularly vulnerable to trampling injuries.

Polar bears (Ursus maritimus)

Stock Definition and Range

Polar bears are circumpolar in their distribution in the northern hemisphere. In Alaska, polar bears have historically been observed as far south in the Bering Sea as St. Matthew Island and the Pribilof Islands (Ray 1971). Two subpopulations, or stocks, occur in Alaska: The Chukchi/Bering Seas stock (CS), and the Southern Beaufort Sea stock (SBS). This final rule primarily discusses the CS stock. A detailed description of the CS and SBS polar bear stocks can be found in the Polar Bear (*Ursus maritimus*) Stock Assessment Reports at *http://alaska.fws.gov/fisheries/mmm/stock/final_sbs_polar_bear_sar.pdf* and *http://alaska.fws.gov/fisheries/mmm/stock/final_cbs_polar_bear_sar.pdf.* A summary of the CS polar bear stock is described below.

The CS stock is widely distributed on the pack ice in the Chukchi Sea and northern Bering Sea and adjacent coastal areas in Alaska and Chukotka, Russia. The northeastern boundary of the CS population is near the Colville Delta in the central Beaufort Sea (Garner *et al.*1990; Amstrup 1995; Amstrup *et al.* 2005) and the western boundary is near the Kolyma River in northeastern Siberia. The population's southern boundary is determined by the extent of annual sea ice in the Bering Sea. It is important to note that the eastern boundary of the CS population constitutes a large overlap zone with bears in the SBS population (Amstrup *et al.* 2004). In this large overlap zone, roughly north of Barrow, Alaska, it is thought that polar bears are approximately 50 percent from the CS population and 50 percent from the SBS population (Amstrup *et al.* 2004; Obbard *et al.* 2010). Currently, capture based studies are being conducted by

the Service in the U.S. portion of the Chukchi Sea to provide updated information on population delineation and habitat use.

Distribution in the Chukchi Sea

Polar bears are common in the Chukchi Sea and their distribution is influenced by the movement of the seasonal pack ice. Polar bears in the Chukchi Sea migrate seasonally with the pack ice but are typically dispersed throughout the region anywhere sea ice and prey may be found (Garner *et al.* 1990; Amstrup 2003). The distance between the northern and southern extremes of the seasonal pack ice in the Chukchi/Bearing Seas is approximately 1,300 km (~807 mi). There may be, however, significant differences year to year. Sea ice throughout the Arctic is changing rapidly and dramatically due to climate change (Douglas 2010). In May and June, polar bears are likely to be encountered over relatively shallow continental shelf waters associated with ice as they move northward from the northern Bering Sea, through the Bering Strait into the southern Chukchi Sea. During the fall and early winter period polar bears are likely to be encountered in the Chukchi Sea during their southward migration in late October and November. Polar bears are dependent upon the sea ice for foraging, and the most productive areas seem to be near the ice edge, leads, or polynyas where the ocean depth is minimal (Durner *et al.* 2004). In addition, polar bears may be present along the shoreline in this area, as they will opportunistically scavenge on marine mammal carcasses washed up along the shoreline (Kalxdorff and Fischbach 1998).

Population Status

The global population estimate of polar bears is approximately 20,000 to 25,000 individuals (Obbard *et al.* 2010). Polar bears typically occur at low densities throughout their circumpolar range (DeMaster and Stirling 1981). The CS stock likely increased after the level of harvest in the United States was reduced subsequent to passage of the MMPA in 1972; however, its status is now considered to be declining based on reported high levels of illegal killing in Russia combined with continued subsistence harvest in the United States, and observed and projected losses in sea ice habitat (Obbard *et al.* 2010). Polar bears in the CS stock are classified as depleted under the MMPA and listed as threatened under the Endangered Species Act of 1973, as amended (ESA)(16 U.S.C. 1531 et seq.). It has been difficult to obtain a reliable population estimate for this stock due to the vast and inaccessible nature of the habitat, movement of bears across international boundaries, logistical constraints of conducting studies in Russian Federation territory, and budget limitations (Amstrup and DeMaster 1988; Garner *et al.* 1992; Garner *et al.* 1998; Evans *et al.* 2003). The recent estimate of the CS stock is approximately 2,000 animals, based on extrapolation of aerial den surveys (Lunn *et al.* 2002; USFWS 2010). Estimates of the stock have been derived from observations of dens and aerial surveys (Chelintsev 1977; Stishov 1991a; Stishov 1991b; Stishov *et al.* 1991); however, these estimates have wide confidence intervals, are considered to be of little value for management, and cannot be used to evaluate status and trend for this stock. Reliable estimates of population size based upon traditional wildlife research methods such as capture-recapture or aerial surveys are not available for this region, and measuring the population size remains a research challenge (Evans *et al.* 2003). Current and new research studies in the United States and Russian Federation are aimed at monitoring population status via ecological indicators (e.g., recruitment rates and body condition) and reducing uncertainty associated with estimates of survival and population size.

Habitat

Polar bears depend on the sea-ice-dominated ecosystem for survival. Polar bears of the Chukchi Sea are subject to the movements and coverage of the pack ice and annual ice as they are dependent on the ice as a platform for hunting, feeding, and mating. Historically, polar bears of the Chukchi Sea have spent most of their time on the annual ice in near-shore, shallow waters over the productive continental shelf, which is associated with the shear zone and the active ice adjacent to the shear zone. Sea ice and food availability are two important factors affecting the distribution of polar bears and their use of habitat. During the ice-covered season, bears use the extent of the annual ice. The most extensive north–south movements of polar bears are associated with the spring and fall ice movement. For example, during the 2006 ice-covered season, six bears radio-collared in the Beaufort Sea were located in the Chukchi and Bering Seas as far south as 59° latitude, which was the farthest extent of the annual ice during 2006. In addition, a small number of bears sometimes remain on the Russian and Alaskan coasts during the initial stages of ice retreat in the spring.

Polar bear distribution during the open-water season in the Chukchi Sea, where maximum open water occurs in September, is dependent upon the location of the ice edge as well. The summer ice pack can be unconsolidated, and segments move great distances by wind, carrying polar bears with them. Recent telemetry movement data are lacking for bears in the Chukchi Sea; however, an increased trend by polar bears to use coastal habitats in the fall during open-water and freeze-up conditions has been noted by researchers since 1992. Recently, during the minimum sea ice extents, which occurred in 2005 and 2007, polar bears exhibited this coastal movement pattern as observations from Russian biologists and satellite telemetry data of bears in the Beaufort Sea indicated that bears were found on the sea ice or along the Chukotka coast during the open-water period.

Changes in sea ice are occurring in the Chukchi Sea because of climate change (Service 2010). With sea ice decreasing, scientists are observing effects of climate change on polar bear habitat, such as an increased amount of open water for longer periods; a reduction in the stable, multi-year ice; and a retraction of sea ice away from productive continental shelf areas (Service 2010). Polar bears using the Chukchi Sea are currently experiencing the initial effects of changes in the sea-ice conditions (Rode and Regehr *et al.* 2007) and will be vulnerable to seasonal changes in sea ice that could limit their access to prey.

As a measure to protect polar bears and their habitat from the effects of climate change, the Service designated critical habitat for polar bear populations in the United States effective January 6, 2011 (75 FR 76086; December 7, 2010). Critical habitat identifies geographic areas that contain features essential for the conservation of an endangered or threatened species, and that may require special management or protection. On January 13, 2013 the U.S. District Court for the District of Alaska issued an order (*Alaska Oil and Gas Association and American Petroleum Institute* v. *Salazar,* Case No. 3:11–cv–0025–RRB) that vacated and remanded the polar bear critical habitat final rule to the Service.

Although the critical habitat final rule has been vacated, the Service still has an obligation to consider the potential impacts of Industry activities upon polar bear habitat. Because the Service believes the habitat identified in the critical habitat final rule is important in any event, our analysis of potential

impacts of Industry activities upon polar bear habitat evaluates impacts on the following habitat types: Barrier island habitat, sea ice habitat (both described in geographic terms), and terrestrial denning habitat (a functional determination). Barrier island habitat includes coastal barrier islands and spits along Alaska's coast, and is used for denning, refuge from human disturbance, access to maternal dens and feeding habitat, and travel along the coast. Sea ice habitat is located over the continental shelf, and includes water 300 m (~984 ft) or less in depth. Terrestrial denning habitat includes lands within 32 km (~20 mi) of the northern coast of Alaska between the Canadian border and the Kavik River, and within 8 km (~5 mi) between the Kavik River and Barrow. The total area designated covers approximately 484,734 sq km (~187,157 sq mi), and is entirely within the lands and waters of the United States.

Important polar bear habitat is described in detail in the final rule that designated polar bear critical habitat (75 FR 76086; December 7, 2010). You can view the rule at: *http://alaska.fws.gov/fisheries/mmm/polarbear/pdf/federal_register_notice.pdf.*

Life History

Polar bears are specially adapted for life in the Arctic and are distributed throughout most ice-covered seas of the circumpolar Northern Hemisphere (Amstrup 2003). They are generally limited to areas where the sea is ice-covered for much of the year; however, polar bears are not evenly distributed throughout their range. They are most abundant near the shore in shallow water areas, and in other areas where currents and ocean upwelling increase marine productivity and maintain some open water during the ice covered season (Stirling and Smith 1975; Stirling *et al.* 1981; Amstrup and DeMaster 1988; Stirling 1990; Stirling and Øritsland 1995; Stirling and Lunn 1997; Amstrup *et al.* 2000; Amstrup 2003). Over most of their range, polar bears remain on the sea ice year-round, or spend only short periods on land (Amstrup 2003).

Denning and Reproduction

Female polar bears without dependent cubs breed in the spring. Females can produce their first litter of cubs at 5 to 6 years of age (Stirling *et al.* 1976; Stirling *et al.* 1977; Lentfer and Hensel 1980; Lentfer *et al.* 1980; Ramsay and Stirling 1982, 1988; Furnell and Schweinsburg 1984; Amstrup 2003). Pregnant females typically enter maternity dens from November through December, and the young are usually born in late December or early January (Lentfer and Hensel 1980; Amstrup 2003). Only pregnant females den for an extended period during the winter; other polar bears may excavate temporary dens to escape harsh winter conditions, but otherwise remain active year-round (Amstrup 2003). Each pregnancy can result in up to three cubs, an average pregnancy results in two cubs being born. The average reproductive interval for a polar bear is 3 to 4 years, and a female polar bear can produce about 8 to 10 cubs in her lifetime. In healthy populations, 50 to 60 percent of the cubs may survive through their first year of life after leaving the den (Amstrup 2003). In late March or early April, the female and cubs emerge from their den. Polar bears have extended maternal care and most dependent young remain with their mother for approximately 2.3 years (Amstrup 2003). If the mother moves young cubs from the den before they can walk or withstand the cold, mortality of the cubs may result. Therefore, it is thought that successful denning, birthing, and rearing activities require a relatively undisturbed environment. Amstrup (2003), however, observed that polar bear females in a den are able to cope with and can display remarkable tolerance for a variety of human disturbance.

Radio and satellite telemetry studies indicate that denning can occur in multi-year pack ice and on land. Recent studies of the SBS indicate that the proportion of dens on pack ice have declined from approximately 60 percent from 1985 to 1994, to 40 percent from 1998 to 2004 (Fischbach *et al.* 2007). In Alaska, areas of maternal polar bear dens of both the CS and SBS stocks appear to be less concentrated than stocks located in Canada and the Russian Federation. Though some variations in denning occur among polar bears from various stocks, there are significant similarities. A common trait of polar bear denning habitat is topographic features that accumulate enough drifted snow for females to excavate a den (Amstrup 2003; Durner *et al.* 2003; Durner *et al.* 2006). Certain areas, such as barrier islands (linear features of low elevation land adjacent to the main coastline that are separated from the mainland by bodies of water), river bank drainages, much of the North Slope coastal plain, and coastal bluffs that occur at the interface of mainland and marine habitat receive proportionally greater use for denning than other areas by bears from the SBS stock (Durner *et al.* 2003; Durner *et al.* 2006). Maternal denning occurs on tundra-bearing barrier islands along the Beaufort Sea and in the large river deltas, such as the Colville and Canning Rivers. Denning of bears from the CS stock occurs primarily on Wrangel and Herald Islands, and on the Chukotka coast in the Russian Federation. Though maternal denning habitat is found on the western coast of Alaska, denning on land for the U.S. portion of the CS stock is not common. However, occasional reports as well as the traditional knowledge of Alaska Natives indicate that it does happen.

Prey

Ringed seals are the primary prey of polar bears in most areas. Bearded seals are also common prey for polar bears in the CS stock. Pacific walrus calves are hunted occasionally, and walrus carcasses are scavenged at haulouts where trampling occurs. Polar bears will occasionally feed on bowhead whale (*Balaena mysticetus*) carcasses opportunistically wherever they may wash ashore and at Point Barrow, Cross Island, and Barter Island, which are areas where the remains of bowhead whales harvested for subsistence purposes are deposited. There are also reports of polar bears killing beluga whales (*Delphinapterus leucas*) trapped in the ice.

Utilization of sea ice is a vital component of polar bear predatory behavior. Polar bears use sea ice as a platform to hunt seals, travel, seek mates, and rest, among other things. They may hunt along leads, polynyas, and other areas of open water associated with sea ice. Polar bears employ a diverse range of methods and tactics to hunt prey. They may wait motionless for extended periods at a seal breathing hole, or may use scent to locate a seal lair then break through the roof; seal lairs are excavated in snow drifts on top of the ice. Polar bears may ambush seals along an ice edge from the ice or from the water. Polar bears also stalk seals hauled out on the ice during warmer weather in the spring. These are just few examples of the predatory methods of polar bears. The common factor is the presence of sea ice in order for polar bears to access prey. Due to changing sea ice conditions, the area and time period of open water and proportion of marginal ice has increased. On average, ice in the Chukchi Sea is melting sooner and retreating farther north each year, and re-forming later. The annual period of time that sea ice is over the shallow, productive waters of the continental shelf is also diminishing. These effects may limit the availability of seals to polar bears, as the most productive areas

for seals appear to be over the shallow waters of the continental shelf.

On December 28, 2012, NMFS issued a final determination to list the ringed and bearded ice seal populations (77 FR 76706 and 77 FR 76740, respectively) that exist in U.S. waters as threatened under the ESA. The loss of ice and snow cover were the most significant conservation concerns in regards to the ice seals, and NMFS concluded that sea ice and snow cover will likely further decrease in the foreseeable future resulting in population declines that threaten the survival of both seal populations.

Mortality

Natural causes of mortality among polar bears are not well understood (Amstrup 2003). Polar bears are long-lived (up to 30 years in captivity); have no natural predators, except other polar bears; and do not appear prone to death by diseases or parasites (Amstrup 2003). Accidents and injuries incurred in the dynamic and harsh sea ice environment, injuries incurred while fighting other bears, starvation (usually during extreme youth or old age), freezing (also more common during extreme youth or old age), and drowning are all known natural causes of polar bear mortality (Derocher and Stirling 1996; Amstrup 2003). Cannibalism by adult males on cubs and other adult bears is also known to occur; however, it is not thought that this is a common or significant cause of mortality. After natural causes and old age, the most significant source of polar bear mortality is from humans hunting polar bears (Amstrup 2003). Other sources of polar bear mortality related to human activities, though few and very rare, include research activities, euthanasia of sick or injured bears, and defense of life kills by non-Natives (Brower *et al.* 2002).

Subsistence Use and Harvest Patterns of Pacific Walruses and Polar Bears

The Alaska Native communities most likely to be impacted by oil and gas activities projected to occur in the Chukchi Sea during the 5-year timeframe of these regulations are: Barrow, Wainwright, Point Lay, Point Hope, Kivalina, Kotzebue, Shishmaref, Little Diomede, Gambell, and Savoonga. However, all communities that harvest Pacific walruses or polar bears in the Chukchi Sea region could be affected by Industry activities. Pacific walruses and polar bears are harvested by Alaska Natives for subsistence purposes. The harvest of these species plays an important role in the culture and economy of many villages throughout northern and western coastal Alaska. Walrus meat is consumed by humans while the ivory is used to manufacture traditional handicrafts. Alaska Natives hunt polar bears primarily for their fur, which is used to manufacture cold weather clothing and handicrafts, but also for their meat.

Under section 101(b) of the MMPA, Alaska Natives who reside in Alaska and dwell on the coast of the north Pacific Ocean or the Arctic Ocean are allowed to harvest walruses and polar bears if such harvest is for subsistence purposes or for purposes of creating and selling authentic Native articles of handicrafts and clothing, as long as the harvest is not done in a wasteful manner. Additionally, and similar to the exemption under the MMPA, section 10(e) of the ESA allows for the continued harvest of species listed as endangered or threatened in Alaska for subsistence purposes.

The sale of handmade clothing and handicrafts made of walrus or polar bear parts is an important source of income in these remote Alaska Native communities. Fundamentally, the production of handicrafts is not a commercial activity, but rather a continuation and adaptation to a market economy of an ancient Alaska Native tradition of making and then bartering handicrafts and clothing for other needed items. The limited cash that Alaska Native villagers can make from handmade clothing and handicrafts is vital to sustain their subsistence hunting and fishing way of life (Pungowiyi 2000).

The Service collects information on the subsistence harvest of Pacific walruses and polar bears in Alaska through the Walrus Harvest Monitor Program (WHMP) and the Marking, Tagging and Reporting Program (MTRP). The WHMP is an observer-based program focused on the harvest of Pacific walruses from the St. Lawrence Island communities Gambell and Savoonga. The MTRP program is administered through a network of ''taggers'' employed in subsistence hunting communities. The marking and tagging rule requires that hunters report harvested walruses and polar bears to MTRP taggers within 30 days of the harvest. Taggers also certify (tag) specified parts (ivory tusks for walruses, hide and skull for polar bears) to help control illegal take and trade. The MTRP reports are thought to underestimate total U.S. Pacific walrus and polar bear subsistence harvest. Harvest levels of polar bears and walruses can vary considerably between years, presumably in response to differences in animal distribution, sea ice conditions, and hunter effort.

In 2010, the Native villages of Gambell and Savoonga adopted local ordinances that limit the number of walruses harvested to four and five per hunting trip, respectively, which likely influences the total number of animals harvested each year. No Chukchi Sea villages have adopted anything similar, but they harvest comparatively few walruses. Information on subsistence harvests of walruses and polar bears in selected communities derived from MTRP harvest reports from 2007 to 2011 is summarized in Table 2.

Table 2. Number of Pacific walruses and polar bears harvested from 2007 to 2011 in 12 Alaska communities, as reported through the U.S. Fish and Wildlife Service (Service) MTRP. Walrus harvest numbers presented here are not corrected for MTRP compliance rates or struck-and-lost estimates.

	Pacific walrus	Polar bear
Barrow	24	49
Gambell	3,069	9
Kivalina	4	3
Kotzebue	2	3
Little Diomede	166	14
Nome	24	1
Point Hope	25	51
Point Lay	10	2
Savoonga	2,918	16
Shishmaref	52	6
Wainwright	71	4
Wales	41	5

Pacific Walrus

Barrow

Barrow is the northernmost community within the geographical region of the final regulations. Most walrus hunting from Barrow occurs in June and July when the landfast ice breaks up and hunters can access walruses by boat as they migrate north on the retreating pack ice. Walrus hunters from Barrow sometimes range up to 60 miles from shore; however, most harvests reported through the MTRP have occurred within 30 miles of the community.

Wainwright

Wainwright hunters have typically harvested more walruses than other mainland coastal subsistence communities on the North Slope. Walruses are thought to represent approximately 40 percent of this communities' annual subsistence diet of marine mammals. Wainwright residents hunt walruses from June through August as the ice retreats northward. Walruses can be plentiful in the pack

ice near the village this time of year. Most of the harvest from Wainwright occurs in June and July. Most walrus hunting is thought to occur within 20 miles of the community, in all seaward directions.

Point Hope

Point Hope hunters typically begin their walrus hunt in late May and early June as walruses migrate north into the Chukchi Sea. The sea ice is usually well off shore of Point Hope by July and does not bring animals back into the range of hunters until late August and September. Most of the reported walrus harvest at Point Hope occurs in the months of June and September. Point Hope harvest occurs mostly within 5 miles of the coast, or near coastal haulout sites at Cape Lisburne.

Point Lay

Point Lay walrus hunting peaks in June and July. Historically, harvests have occurred primarily within 40 miles north and south along the coast from Point Lay and approximately 30 miles offshore. Beginning in 2010, walruses started hauling out on the barrier island about 4 miles north of Point Lay in August and remain there until late September to early October. This provides Point Lay hunters with new opportunities to harvest walruses, and reports indicate that from two to five animals are harvested at that time of year. Hunters harvest during the early stages of haulout formation and as the haulout begins to dissipate to avoid creating a disturbance resulting in a large stampede.

St. Lawrence Island

St. Lawrence Island is located in the Bering Sea south of the Bering Strait. The two communities on the island are Gambell, on western tip, and Savoonga on the north central shore. These two subsistence hunting communities account for the majority of the Pacific walrus harvest in Alaska. Most of the walrus harvest from Gambell and Savoonga takes place in the spring, but some harvest also takes place in the fall and winter, depending on ice and weather conditions. Hunters from Gambell typically use areas north and east of the island while hunters from Savoonga traditionally utilize areas north, west, and south of the island. St. Lawrence Island hunters will typically travel from 40 to 60 miles, and as much as 90 miles, out to sea to find walruses. The consumption of traditional subsistence foods, such as marine mammals, and the economic value of marine mammal parts, such as walrus ivory, is thought to be more significant in Gambell and Savoonga than in communities on the mainland coast of Alaska.

Polar Bears

Polar bears are harvested by Alaska Natives for subsistence and handicraft purposes. This species plays an important role in the culture and economy of many villages throughout western and northern coastal Alaska, where the polar bear figures prominently in Alaska Native stories, art, traditions, and cultural activities. In these northern and western coastal Alaskan Native villages, the taking and use of the polar bear is a fundamental part of Alaska Native culture. For Alaska Natives engaged in subsistence uses, the very acts of hunting, fishing, and gathering, coupled with the seasonal cycle of these activities and the sharing and celebrations that accompany them, are intricately woven into the fabric of their social, psychological, and religious life (Pungowiyi 2000).

Polar Bear Harvest Patterns in Alaska

The following summary is excerpted from the *Report of the Scientific working group to the US-Russian Federation Polar Bear Commission (May 2010),* which describes the history of the polar bear harvest during the last century. A more detailed description can be found at: *http://alaska.fws.gov/fisheries/mmm/polarbear/bilateral.htm:*

Prior to the 20th century Alaska's polar bears were hunted primarily by Alaska Natives for subsistence purposes although commercial sales of hides occurred primarily as a result of Yankee whaling and arctic exploration ventures. During the 20th century, polar bears were harvested for subsistence, handicrafts, and recreational sport hunting. Based on records of skins shipped from Alaska for 1925 to 1953, the estimated annual statewide harvest averaged 120 bears and this take was primarily by Native hunters. Recreational hunting by non-Native sport hunters using aircraft became popular from 1951 to 1972, increasing the statewide annual harvest to 150 during 1951 to 1960 and to 260 during 1960 to 1972 (Amstrup *et al.* 1986). During the late 1960s and 1970s the size of the Beaufort Sea stock declined substantially (Amstrup *et al.* 1986) due to excessive sport harvest. Hunting by non-Natives was prohibited in 1973 when provisions of the Marine Mammal Protection Act (MMPA) went into effect. The prohibition of non-Native sport hunting led to a reduction in the annual harvest of polar bears from the Alaska-Chukotka population from 189 ± 50 bears/year for the period 1961 to 1972 to 80 ± 54 bears/year for the period 1973 to 1984 (Amstrup *et al.* 1986; Fig. 1). According to Service harvest records, from 1980 through the present, harvest of the Alaska-Chukotka population in the U.S. portion has declined. Reasons for a decline in the Alaska native subsistence harvest are currently unknown, but are currently being investigated. Possible causes include decreased hunter effort, decreased polar bear numbers, changes in polar bear distribution, and environmental conditions that make polar bears less available to hunters.

As stated previously, harvest levels of polar bears can vary considerably between years for a variety of reasons, including annual variations in animal distribution, sea ice conditions, and hunter effort. Table 2 summarizes MTRP harvest reports for polar bears for selected western Alaska communities from 2007 to 2011, the most recent 5-year period for which complete data are available. The harvest information in Table 2 provides an insight into the level of polar bear harvest by western Alaska communities during the previous 5-year period of Chukchi Sea ITRs. Average polar bear harvest levels in Alaska have remained relatively stable over the past 20 years in the Southern Beaufort Sea, but have declined in the Chukchi/Bering seas. Over these past 20 years, six communities (Barrow, Point Hope, Savoonga, Gambell, Little Diomede, and Wainwright) consistently account for the majority of all polar bears harvested in Alaska. The reason for the decline in harvest in western Alaska is unknown, but could be a result of reduced hunter effort, changing distribution of bears, and/or a decline in the number of bears in the population.

Polar bears are harvested throughout the calendar year, depending on availability. Hunters in western Alaska, from Point Lay to St. Lawrence Island, usually harvest bears in winter, since bears moving southward with the advancing pack ice are more available in those areas later in the season. The number of polar bears harvested from Barrow is thought to be influenced by sea ice conditions as well as the number of people engaged in subsistence activities. Most polar bear harvests reported by Barrow occurred in February and March. Polar bears are harvested from Wainwright throughout much of the year, with peak harvests reported in May and December within 10 miles of the community. Polar bears are typically harvested from Point Hope from January to April within 10 miles of the community; however, Point Hope hunters reported taking polar bears as far away as Cape Thompson and Cape Lisburne.

Although few people are thought to hunt specifically for polar bears, those that do hunt primarily between October and March. Polar bears are often harvested coincidentally with beluga and bowhead whale harvests. Hunting

areas for polar bears overlap strongly with areas of bowhead subsistence hunting, particularly the area from Point Barrow South to Walakpa Lagoon where walrus and whale carcasses are known to concentrate polar bears.

Harvest Management of Polar Bears in Alaska

The Service works through existing co-management agreements with Alaska Natives to address future actions that affect polar bears and polar bear hunting. This includes working with the Alaska Nanuuq Commission (ANC), the NSB and its Native-to-Native Agreement with the Inuvialuit Game Council of Canada (Beaufort Sea region), and the Joint Commission formed with the Russian Federation under the Bilateral Agreement (Chukchi/Bering seas region).

The ANC was formed in 1994, to represent the villages in North and Northwest Alaska on matters concerning the conservation and sustainable subsistence use of the polar bear. The mission of ANC is to ''conserve Nanuuq and the Arctic ecosystem for present and future generations of Arctic Alaska Natives.'' The tribal council of each member village has passed a resolution to become a member and to authorize the ANC to represent them on matters concerning the polar bear at regional and international levels. Fifteen villages are currently members: Barrow; Wainwright; Kotzebue; Nuiqsut; Savoonga; Kaktovik; Point Lay; Point Hope; Brevig Mission; Shishmaref; Gambell; King Island; Wales; Little Diomede; and Kivalina.

Polar bears harvested from the communities of Barrow, Nuiqsut, Kaktovik, Wainwright, and Atqasuk are currently considered part of the SBS stock and thus are subject to the terms of the Inuvialuit-Inupiat Polar Bear Management Agreement (Inuvialuit-Inupiat Agreement).

The Inuvialuit-Inupiat Agreement establishes quotas and recommendations concerning protection of denning females, family groups, and methods of harvest. Adherence to the quota is voluntary in the United States, and it has generally been followed since implementation of the Inuvialuit-Inupiat Agreement (Brower *et al.* 2002). Under the Inuvialuit-Inupiat Agreement, quotas are recommended by technical advisors based on estimates of population size and age specific estimates of survival and recruitment. The current quota of 70 total bears per year was established in July 2010, and represents a decrease from the previous quota of 80 total bears per year (Brower *et al.* 2002). The quota is allocated to Canadian Inuvialuit and to Alaskan Inupiat, with 35 bears each. The Inuvialuit-Inupiat Agreement and its quotas are voluntary between the Inupiat and Inuvialuit, and are not enforceable by any law or authority of the governments of the United States or Canada.

The ''*Agreement Between the Government of the United States of America and the Government of the Russian Federation on the Conservation and Management of the Alaska–Chukotka Polar Bear Population,*'' signed in Washington, DC, on October 16, 2000 (the 2000 Agreement), provides legal protections for the population of polar bears found in the Chukchi–Northern Bering Sea. The 2000 Agreement is implemented in the United States through Title V of the Marine Mammal Protection Act (MMPA) (16 U.S.C. 1361 et seq.) and builds upon those protections already provided to this population of polar bears through the ''Agreement on the Conservation of Polar Bears,'' executed in Oslo, Norway on November 13, 1973 (the 1973 Agreement), which was a significant early step in the international conservation of polar bears.

The 1973 Agreement is a multilateral treaty to which the United States and Russia are parties with other polar bear range states: Norway, Canada, and Denmark. While the 1973 Agreement provides authority for the maintenance of a subsistence harvest of polar bears and provides for habitat conservation, the 2000 Agreement specifically establishes a common legal, scientific, and administrative framework for the conservation and management of the Alaska–Chukotka polar bear population between the United States and Russia.

The 2000 Agreement requires the United States and the Russian Federation to manage and conserve polar bears based on reliable science and to provide for subsistence harvest by native peoples. The U.S.–Russian Federation Polar Bear Commission (Commission), which functions as the bilateral managing authority, consists of a Native and Federal representative of each country. The Commission is advised by a 16-member Scientific Working Group (SWG), including experts on ice habitat, bear ecology and population dynamics, and traditional ecological knowledge.

Meetings of the Commission have occurred yearly since 2009. At the fourth meeting of the Commission, which took place from June 25 through 27, 2012, in Anchorage, Alaska, United States, the Commission, based on the recommendation of the SWG, agreed that no change was necessary to the sustainable harvest level identified in 2010. In 2012, the Commission adopted a 5-year sustainable harvest level of 290 polar bears with no more than one third to be female, with the requirements that the 5-year sustainable harvest level be allocated over the 5-year period using methods recognized by the SWG as biologically sound, and that these methods include the identification of annual sustainable harvest levels, for consideration by the Commission in setting annual taking limits. This cooperative management regime for the subsistence harvest of bears is key to both providing for the long term viability of the population as well as addressing the social, cultural, and subsistence interests of Alaska Natives and the native people of Chukotka.

Potential Effects of Oil and Gas Industry Activities on Pacific Walruses and Polar Bears

Industry activities can affect individual walruses and polar bears in numerous ways. The petitioners in sections 6.1 and 6.2 of the AOGA Petition describe anticipated impacts *for Incidental Take Regulations for Oil and Gas Activities in the Chukchi Sea and Adjacent Lands in 2013 to 2018,* January 31, 2012. Potential effects, detailed below, from Industry activities could include: (1) Disturbance due to noise; (2) physical obstructions; (3) human encounters; and (4) effects on prey.

A thorough discussion of the impacts of Industry activities in the Chukchi Sea on marine mammals is found in the Chukchi Sea Final Environmental Impact Statement (EIS) at *http://www.boem.gov/uploadedFiles/BOEM/About_BOEM/BOEM_Regions/Alaska_Region/Environment/Environmental_Analysis/2007-026-Vol%20I.pdf* and the Chukchi Sea Final Supplemental EIS, Chukchi Sea Planning Area, Oil and Gas Lease Sale 193 at *http://www.boem.gov/About-BOEM/BOEM-Regions/Alaska-Region/Environment/Environmental-Analysis/OCS-EIS/EA-BOEMRE-2011-041.aspx.*

Pacific Walruses

Oil and gas exploration activities in the Chukchi Sea region include the operation of seismic survey vessels, drillships, icebreakers, supply boats, fixed wing aircrafts, and helicopters. These activities could disturb walruses. Walruses that are disturbed may experience insufficient rest, increased stress and energy expenditure, interference with feeding, and masking of communication. Cows with calves that experience disturbance may alter their care of calves, such as staying in

the water longer or nursing less frequently. Calves that experience disturbance could spend an increased amount of time in the water, affecting their thermoregulation. Prolonged or repeated disturbances could potentially displace individuals or herds from preferred feeding or resting areas. Disturbance events could cause walrus groups to abandon land or ice haulouts.

The response of walruses to disturbance stimuli is highly variable. Observations by walrus hunters and researchers suggest that males tend to be more tolerant of disturbances than females and individuals tend to react less than groups. Females with dependent calves are considered the least tolerant of disturbances. Hearing sensitivity is assumed to be within the 13 Hz and 1,200 Hz range of their own vocalizations. Walrus hunters and researchers have noted that walruses tend to react to the presence of humans and machines at greater distances from upwind approaches than from downwind approaches, suggesting that odor is also a stimulus for a flight response. The visual acuity of walruses is thought to be less than for other species of pinnipeds (Kastelein *et al.* 1993).

Walruses must periodically haul out onto ice or land to rest between feeding bouts. Aerial surveys in the eastern Chukchi Sea found that 80 to 96 percent of walruses were closely associated with sea ice and that the number of walruses observed in open water decreased significantly with distance from the pack ice. Under minimal or no ice conditions, walruses either follow the ice out of the region, or relocate to coastal haulouts where their foraging trips are usually restricted to near shore habitats. However, in 2010 and 2011, more than 20,000 walruses hauled out near Point Lay and many traveled to the Hanna Shoal area to feed, returning to Point Lay. Therefore, in evaluating the potential impacts of exploration activities on walruses, the presence or absence of pack ice serves as one indicator of whether or not walruses are likely to be found in the area. In addition, if walruses are using coastal haulouts near Point Lay, or farther north, many walruses could be encountered in the water over or near Hannah Shoal as well as between the haul out area and Hanna Shoal (Jay *et al.* 2012; Delarue *et al.* 2012). Activities occurring in or near sea ice habitats or areas of high benthic productivity have the greatest potential for affecting walruses. Activities occurring during the open-water period away from known feeding areas are expected to affect relatively small numbers of animals except as described above in regards to walruses moving between coastal haulouts and offshore feeding areas.

1. Disturbance From Noise

Noise generated by Industry activities, whether stationary or mobile, has the potential to disturb walruses. Potential impacts of Industry-generated noise include displacement from preferred foraging areas, increased stress and energy expenditure, interference with feeding, and masking of communications. Most impacts of Industry noise on walruses are likely to be limited to a few groups or individuals rather than the population due to their geographic range and seasonal distribution within the geographic region. Reactions of marine mammals to noise sources, particularly mobile sources such as marine vessels, vary. Reactions depend on the individuals' prior exposure to the disturbance source, their need or desire to be in the particular habitat or area where they are exposed to the noise, and visual presence of the disturbance sources.

Unobserved impacts to walruses due to aquatic and airborne noises may occur, but cannot be estimated. Airborne noises have the greatest potential to impact walruses occurring in large numbers at coastal haulouts or on ice floes near Industry activities. However, restrictions on aircraft altitude and offset distances, as well as the 25-mile coastal exclusion zone enacted by BOEM, adequately mitigate this potential impact of Industry activities when walruses are on land. A detailed discussion of noise disturbance in the marine environment follows.

A. Stationary Sources

An exploratory drill rig is an example of a stationary source of sounds, odors, and visual stimuli. In estimating impacts, it is difficult to separate those stimuli. However, walruses appear to rely primarily on auditory and olfactory senses, and then sight when responding to potential predators or other stimuli (Kastelein *et al.* 1993). Industrial ambient noise associated with the drilling operations, such as generators and other equipment, is expected. Walruses may respond to sound sources by either avoidance or tolerance. Typically, walruses will avoid a disturbance by moving away.

In one reported observation in 1989 by Shell Western E & P, Inc., a single walrus actually entered the moon pool of a stationary drillship several times during a drilling operation. A moon pool is the opening to the sea on a drillship for a marine drill apparatus. The drill apparatus protrudes from the ship through the moon pool to the sea floor. Eventually, the walrus had to be removed from the ship for its own safety. During the same time period, Shell Western E & P, Inc., also reported encountering multiple walruses close to their drillship during offshore drilling operations in the Chukchi Sea.

B. Mobile Sources

Seismic operations are expected to add significant levels of noise into the marine environment. Although the hearing sensitivity of walruses is poorly known, source levels associated with Marine 3D and 2D seismic surveys are thought to be high enough to cause temporary hearing loss in other pinniped species. Therefore, walruses found near source levels within the 180-decibel (dB re 1 μPa at 1 m) ensonification zone described by Industry for seismic activities could potentially suffer shifts in hearing thresholds and temporary hearing loss. Ensonification zones are a proxy for the amount of sound or seismic disturbance that would be considered to rise to the level of biologically significant disturbance, i.e., Level B take. Seismic survey vessels will be required to ramp up airguns slowly to allow marine mammals the opportunity to move away from potentially injurious sound sources. Marine mammal monitors will also be required to monitor seismic safety zones and call for the power down or shutdown of airgun arrays if any marine mammals are detected within the prescribed safety zone.

Geotechnical seismic surveys and high resolution site clearance seismic surveys are expected to occur primarily in open water conditions, at a sufficient distance from the pack ice and large concentrations of walruses to avoid most disturbances. Although most walruses are expected to be closely associated with sea ice or coastal haulouts during offshore exploration activities, animals may be encountered in open water conditions. Walruses swimming in open water would likely be able to detect seismic airgun pulses up to several kilometers from a seismic source vessel. The most likely response of walruses to noise generated by seismic surveys would be to move away from the source of the disturbance. Because of the transitory nature of the proposed seismic surveys, impacts to walruses exposed to seismic survey operations are expected to be temporary in nature and have little or no effects on survival or recruitment.

Although concentrations of walruses in open water environments are

expected to be low, groups of foraging or migrating animals transiting through the area may be encountered. Adaptive mitigation measures (e.g., avoidance distance guidelines, seismic airgun shutdowns) based upon monitoring information will be implemented to mitigate potential impacts to walrus groups feeding or traveling in offshore locations and ensure that these impacts would be limited to small numbers of animals.

C. Vessel Traffic

Offshore drilling exploration activities are expected to occur primarily in areas of open water some distance from the pack ice; however, support vessels and/or aircraft may occasionally encounter aggregations of walruses hauled out onto sea ice. The sight, sound, or smell of humans and machines could potentially displace these animals from ice haulouts. The reaction of walruses to vessel traffic is dependent upon vessel type, distance, speed, and previous exposure to disturbances. Generally, walruses react to vessels by leaving the area, but we are aware of at least one occasion where an adult walrus used a vessel as a haulout platform in 2009. Walruses in the water appear to be less readily disturbed by vessels than walruses hauled out on land or sea ice, and it appears that low frequency diesel engines cause less of a disturbance than high frequency outboard engines. In addition, walrus densities within their normal distribution are highest along the edge of the pack ice, and Industry vessels typically avoid these areas. Furthermore, barges and vessels associated with Industry activities travel in open water and avoid large ice floes or land where walruses will be found.

Monitoring programs associated with exploratory drilling operations in the Chukchi Sea in 1989 and 1990 noted that 25 to 60 percent, respectively, of walrus groups encountered in the pack ice during icebreaking responded by ''escaping'' (Brueggeman *et al.* 1990, 1991). Escape was not defined, but we assume that walruses escaped by abandoning the ice and swimming away. Ice management operations are expected to have the greatest potential for disturbances since these operations typically require vessels to accelerate, reverse direction, and turn rapidly, activities that maximize propeller cavitations and resulting noise levels. Previous studies (Brueggeman *et al.* 1990, 1991) suggest that icebreaking activities can displace some walrus groups up to several miles away; however, most groups of walruses resting on the ice showed little reaction when they were beyond 805 m (0.5 mi) from the activity.

When walruses are present, underwater noise from any vessel traffic in the Chukchi Sea may ''mask'' ordinary communication between individuals and prevent them from locating each other. It may also prevent walruses from using potential habitats in the Chukchi Sea and may have the potential to impede movement. Vessel traffic will likely increase if offshore Industry expands and may increase if warming waters and seasonally reduced sea ice cover alter northern shipping lanes.

Impacts associated with transiting support vessels and aircrafts are likely to be widely distributed throughout the area. Therefore, noise and disturbance from aircraft and vessel traffic associated with exploration projects are expected to have localized, short-term effects. Nevertheless, the potential for disturbance events resulting in injuries, mortalities, or cow-calf separations is of concern. The potential for injuries, though unlikely, is expected to increase with the size of affected walrus aggregations. Adaptive mitigation measures (e.g., distance restrictions, reduced vessel speeds) designed to separate Industry activities from walrus aggregations at coastal haulouts and in sea ice habitats are expected to reduce the potential for animal injuries, mortalities, and cow-calf separations.

While drilling operations are expected to occur during open water conditions, the dynamic movements of sea ice could transport walruses hauled out on ice within range of drilling operations. Any potential disturbance to walruses in this condition would be through ice management practices, where ice management may displace walruses from ice in order to prevent displacement of the drill rig. Mitigation measures specified in an LOA may include: Requirements for ice scouting; surveys for walruses and polar bears near active drilling operations and ice breaking activities; requirements for marine mammal observers onboard drillships and ice breakers; and operational restrictions near walrus and polar bear aggregations. These measures are expected to reduce the potential for interactions between walruses and drilling operations.

Ice floes that threaten drilling operations may have to be intercepted and moved with a vessel, and those floes could be occupied by resting walruses. Observations by icebreaker operators suggest that most walruses will abandon drifting ice floes long before they reach drilling rigs and before ice management vessels need to intercept a floe that has to be deflected or broken. Ice management activities that cause walruses to flush from or abandon ice will be considered as intentional takes by the Service. Given the observations from previous operations (Brueggeman *et al.* 1990, 1991), we expect this to be a rare event and involve only small numbers of animals. In addition, Industry has developed an adaptive ice management procedure that requires case-by-case approval by Service officials prior to managing ice occupied by walruses. If ice threatening drilling operations is too large and thick to be moved, drilling operations will be suspended, the well would be capped, and the drill vessel would be moved until the ice passes. For example, in 2012, ice management was required during a total of seven days from 31 August to 13 September and was limited to nine discrete isolated events, where ice was broken apart only two times at the Burger A prospect. During the drilling season the drill ship had to be moved off-site for 10 days due to encroachment of ice floes.

D. Aircraft Traffic

Aircraft overflights may disturb walruses. Reactions to aircraft vary with range, aircraft type, and flight pattern, as well as walrus age, sex, and group size. Adult females, calves, and immature walruses tend to be more sensitive to aircraft disturbance. Fixed wing aircraft are less likely to elicit a response than are helicopters. Walruses are particularly sensitive to changes in engine, propeller, or rotor noise and are more likely to stampede when aircraft turn sharply while accelerating or fly low overhead. Researchers conducting aerial surveys for walruses in sea ice habitats have observed less reaction to fixed wing aircraft above 457 m (1,500 ft) (Service unpubl. data). Although the intensity of the reaction to noise is variable, walruses are probably most susceptible to disturbance by fast-moving and low-flying aircraft, with helicopters usually causing the strongest reactions.

2. Physical Obstructions

It is unlikely that walrus movements would be displaced by offshore stationary facilities, such as an exploratory drill rig. Vessel traffic could temporarily interrupt the movement of walruses, or displace some animals when vessels pass through an area. This displacement would probably have minimal or no effect on animals and would last no more than a few hours.

3. Human Encounters

Human encounters with walruses could occur during Industry operations. These types of encounters will most likely be associated with support activities in the coastal environments near walrus coastal haulouts. Disturbance events could result in trampling injuries or cow-calf separations, both of which are potentially fatal. Calves and young animals at the perimeter of the herds appear particularly vulnerable to trampling injuries. Mortalities from trampling are most severe when large numbers of walruses resting on land are disturbed and flee *en masse* to the ocean. In 2007, more than 3,000 calves died along the Chukotka coast due to stampedes caused by humans and polar bears. Since then, mortalities in the Russian Federation and the United States have been fewer than 700 per year. This type of disturbance from Industry activity is considered highly unlikely. Areas where and when walrus coastal haulouts form in the United States will be protected with additional mitigation measures, such as activity exclusion zones, airspace restrictions, and close monitoring.

4. Effect on Prey Species

Walruses feed primarily on immobile benthic invertebrates. The effect of Industry activities on benthic invertebrates most likely would be from oil discharged into the environment. Oil has the potential to impact walrus prey species in a variety of ways including, but not limited to, mortality due to smothering or toxicity, perturbations in the composition of the benthic community, and altered metabolic and growth rates. The low likelihood of an oil spill large enough to affect prey populations (see analysis in the section titled Potential Impacts of Waste Product Discharge and Oil Spills on Pacific Walruses and Polar Bears, Pacific Walrus subsection) indicates that Industry activities will likely have limited effects on walruses through effects on prey species.

Evaluation of Anticipated Effects on Walruses

Based on our review of the activities; existing operating conditions and mitigation measures; information on the biology, ecology, and habitat use patterns of walruses in the Chukchi Sea; information on potential effects of oil and gas activities on walruses; and the results of previous monitoring efforts associated with Industry activity in the Chukchi as well as the Beaufort Sea, we conclude that, while the incidental take (by harassment) of walruses is reasonably likely to or reasonably expected to occur as a result of the activities, the anticipated takes will be limited to minor behavioral modifications due to temporary, nonlethal disturbances. These behavioral changes are not outside the subspecies' normal range of activity and are not reasonably expected to, or likely to, affect rates of overall population recruitment or survival. Our review of the nature and scope of the activities, when considered in light of the observed impacts of past exploration activities by Industry, indicates that it is unlikely that there will be any lethal take of walruses associated with these activities or any impacts on survival or reproduction.

Polar Bears

In the Chukchi Sea, polar bears will have a limited presence during the open-water season associated with Industry operations. This is because most bears move with the ice to the northern portion of the Chukchi Sea and distribute along the pack ice during this time, which is outside of the geographic region of the final regulations. Additionally, they are found more frequently along the Chukotka coastline in the Russian Federation. This limits the probability of major impacts on polar bears from offshore Industry activities in the Alaskan portion of the Chukchi Sea. Although polar bears have been observed in open water, miles from the ice edge or ice floes, this has been a relatively rare occurrence.

Polar bears will be present in the region of activity in limited numbers and, therefore, oil and gas activities could affect polar bears in various ways during both offshore and onshore activities, through: (1) Impacts from offshore activities; (2) impacts from onshore activities; (3) impacts from human encounters; (4) effects on prey species; and (5) effects on polar bear habitat are described below.

1. Offshore Activities

In the open-water season, Industry activities will be limited to vessel-based exploration activities, such as exploratory drilling and seismic surveys. These activities avoid ice floes and the multi-year ice edge; however, they could contact a limited number of bears in open water and on ice floes.

A. Vessel Activities

Vessel-based activities, including operational support vessels, such as barges, supply vessels, oil spill response, and ice management vessels, in the Chukchi Sea could affect polar bears in a number of ways. Seismic ships, icebreakers, or the drilling rig may become physical obstructions to polar bear movements, although these impacts will be short-term and localized. Likewise, noise, sights, and smells produced by exploration activities could disrupt their natural behavior by repelling or attracting bears to human activities.

Polar bears are curious and tend to investigate novel sights, smells, and noises. If bears are present, noise produced by offshore activities could elicit several different responses in individual polar bears. Noise may act as a deterrent to bears entering the area of operation, or the noise could potentially attract curious bears.

In general, little is known about the potential for seismic survey sounds to cause auditory impairment or other physical effects in polar bears. Researchers have studied the hearing sensitivity of polar bears to understand how noise can affect polar bears, but additional research is necessary to understand the potential negative effects of noise (Nachtigall *et al.* 2007; Owen and Bowles 2011). Available data suggest that such effects, if they occur at all, would be limited to short distances from the sound source and probably to projects involving large airgun arrays. Polar bears swim predominantly with their heads above the surface, where underwater noises are weak or undetectable, and this behavior may naturally limit noise exposure to polar bears. There is no evidence that airgun pulses can cause serious injury or death to bears, even in the case of large airgun arrays.

Additionally, the planned monitoring and mitigation measures include shutdowns of the airguns, which would reduce any such effects that might otherwise occur if polar bears are observed in the ensonification zones. Thus, it is doubtful that any single bear will be exposed to strong underwater seismic sounds long enough for significant disturbance, such as an auditory injury, to occur.

Though polar bears are known to be extremely curious and may approach sounds and objects to investigate, they are also known to move away from sources of noise and the sight of vessels, icebreakers, aircraft, and helicopters. The effects of retreating from vessels or aircraft may be minimal if the event is short and the animal is otherwise unstressed. For example, retreating from an active icebreaker may produce minimal effects for a healthy animal on a cool day; however, on a warm spring or summer day, a short run may be

enough to overheat a well-insulated polar bear.

As already stated, polar bears spend the majority of their time on pack ice during the open-water season in the Chukchi Sea or along the Chukotka coast, which limits the potential of impacts from human and Industry activities in the geographic region. In recent years, the Chukchi Sea pack ice has receded over the Continental Shelf during the open-water season. Although this poses potential foraging ramifications, by its nature the exposed open water creates a barrier between the majority of the ice-pack-bound bear population and human activity occurring in open water, thereby limiting potential disturbance.

Bears in water may be in a stressed state if found near Industry sites. Researchers have recently documented that bears occasionally swim long distances during the open-water period seeking either ice or land. They suspect that the bears may not swim constantly, but find solitary icebergs or remnants to haulout on and rest. The movement is becoming more common, but highlights the ice-free environment that bears are being increasingly exposed to that requires increased energy demands. In one study (between 2004 through 2009), researchers noted that 52 bears embarked on long-distance swim events. In addition, they documented 50 swims that had an average length of 96 miles. They noted that long-distance swim events are still uncommon, but 38 percent of collared bears took at least one long-distance swim (Pagano *et al.* 2012).

The majority of vessels, such as seismic boats and barges, associated with Industry activities travel in open water and avoid large ice floes. Some, such as ice management vessels, operate in close proximity to the ice edge and unconsolidated ice during open-water activities. Vessel traffic could encounter an occasional bear swimming in the open water. However, the most likely habitat where bears will be encountered during the open-water season is on the pack ice edge or on ice floes in open water. During baseline studies conducted in the Chukchi Sea between 2008 and 2010, 14 of 16 polar bears encountered by a research vessel were observed on the ice, while the remaining two bears were observed in the water swimming (USFWS unpublished data).

If there is an encounter between a vessel and a polar bear, it will most likely result in temporary behavioral disturbance only. In open water, vessel traffic could result in short-term behavioral responses to swimming polar bears through ambient noise produced by the vessels, such as underwater propeller cavitation, or activities associated with them, such as on-board machinery, where a bear will most likely swim away from the vessel. Indeed, observations from monitoring programs report that when bears are encountered in open water swimming, bears have been observed retreating from the vessel as it passes (USFWS unpublished data).

Polar bears could be encountered if a vessel is operating in ice or near ice floes, where the response of bears on ice to vessels is varied. Bears on ice have been observed retreating from vessels; exhibiting few reactions, such as a cessation in activity or turning their head to watch the vessel; and exhibiting no perceived reaction at all to the vessel. Bears have also been observed approaching vessels in the ice.

B. Aircraft

Routine, commercial aircraft traffic flying at high altitudes (approximately 10,000 to 30,000 feet above ground level (AGL)) appears to have little to no effect on polar bears; however, extensive or repeated over-flights of fixed wing aircraft or helicopters could disturb polar bears. A minimum altitude requirement of 1,500 feet for aircraft associated with Industry activity will help mitigate disturbance to polar bears. Behavioral reactions of polar bears are expected to be limited to short-term changes in behavior that will have no long-term impact on individuals and no identifiable impacts on the polar bear population.

In summary, while offshore, open-water seismic exploration activities could encounter polar bears in the Chukchi Sea during the latter part of the operational period, it is unlikely that exploration activities or other geophysical surveys during the open-water season would result in more than temporary behavioral disturbance to polar bears. Any disturbance would be visual and auditory in nature, and likely limited to deflecting bears from their route. Seismic surveys are unlikely to cause serious impacts to polar bears as they normally swim with their heads above the surface, where noises produced underwater are weak, and polar bears rarely dive below the surface. Ice management activities in support of the drilling operation have the greatest potential to disturb bears by flushing bears off ice floes when moving ice out of the path of the drill rig.

Monitoring and mitigation measures required for open water, offshore activities will include, but will not be limited to: (1) A 0.5-mile operational exclusion zone around polar bear(s) on land, ice, or swimming; (2) marine mammal observers (MMOs) on board all vessels; (3) requirements for ice scouting; (4) surveys for polar bears in the vicinity of active operations and ice breaking activities; and (5) operational restrictions near polar bear aggregations. We expect these mitigation measures will further reduce the potential for interactions between polar bears and offshore operations.

2. Onshore Activities

While no large exploratory programs, such as drilling or seismic surveys, are currently being developed for onshore sites in the Chukchi Sea geographic area, land-based support facilities, maintenance of the Barrow Gas Fields, and onshore baseline studies may contact polar bears. Bear-human interactions at onshore activities are expected to occur mainly during the fall and ice-covered season when bears come ashore to feed, den, or travel. Noise produced by Industry activities during the open-water and ice-covered seasons could potentially result in takes of polar bears at onshore sites. Noise disturbance could originate from either stationary or mobile sources. Stationary sources include support facilities. Mobile sources can include vehicle and aircraft traffic in association with Industry activities, such as ice road construction. The effects for these sources are described below.

A. Noise

Noise produced by onshore Industry activities could elicit several different responses in polar bears. The noise may act as a deterrent to bears entering the area, or the noise could potentially attract bears. Noise attracting bears to Industry activities, especially activities in the coastal or nearshore environment, could result in bear-human interactions, which could result in unintentional harassment, deterrence (under a separate authorization), or lethal take of the bear. Unintentional harassment would most likely be infrequent, short-term, and temporary by either attracting a curious bear to the noise or causing a bear to move away. Deterrence by nonlethal harassment to move a bear away from humans would be much less likely, infrequent, short-term, and temporary. Lethal take of a polar bear from bear-human interaction related to Industry activity is extremely unlikely (discussed in the Analysis of Impacts of the Oil and Gas Industry on Pacific Walruses and Polar Bears in the Chukchi Sea).

During the ice-covered season, noise from onshore activities could deter

females from denning in the surrounding area, given the appropriate conditions, although a few polar bears have been known to den in proximity to industrial activity. Only a minimal amount of denning by polar bears has been recorded on the western coast of Alaska; however, onshore activities could affect potential den habitat and den site selection if they were located near facilities. However, with limited onshore denning, Industry impacts to onshore denning are expected to be minimal.

Known polar bear dens around the oil and gas activities are monitored by the Service, when practicable. Only a small percentage of the total active den locations are known in any year. Industry routinely coordinates with the Service to determine the location of Industry's activities relative to known dens and den habitat. Implementation of mitigation measures, such as the one-mile operational exclusion area around known dens or the temporary cessation of Industry activities, will ensure that disturbance is minimized.

B. Aircraft

As with offshore activities, routine high altitude aircraft traffic will likely have little to no effect on polar bears; however, extensive or repeated low altitude over-flights of fixed wing aircraft for monitoring purposes or helicopters used for re-supply of Industry operations could disturb polar bears on shore. Behavioral reactions of non-denning polar bears are expected to be limited to short-term changes in behavior and would have no long-term impact on individuals and no impacts on the polar bear population. Mitigation measures, such as minimum flight elevations over polar bears or areas of concern and flight restrictions around known polar bear dens, will be required, as appropriate, to reduce the likelihood that bears are disturbed by aircraft.

3. Human Encounters

While more polar bears transit through the coastal areas than inland, we do not anticipate many bear-human interactions due to the limited amount of human activity that has occurred on the western coast of Alaska. Near-shore activities could potentially increase the rate of bear-human interactions, which could result in increased incidents of harassment of bears. Industry currently implements company policies, implements interaction plans, and conducts employee training to reduce and mitigate such encounters under the guidance of the Service. The history of the effective application of interaction plans has shown reduced interactions between polar bears and humans and no injuries or deaths to humans since the implementation of incidental take regulations.

Industry has developed and uses devices to aid in detecting polar bears, including human bear monitors, remote cameras, motion and infrared detection systems, and closed circuit TV systems. Industry also takes steps to actively prevent bears from accessing facilities using safety gates and fences. The types of detection and exclusion systems are implemented on a case-by-case basis with guidance from the Service.

Bear-human interactions will be mitigated through conditions in LOAs, which require the applicant to develop a polar bear interaction plan for each operation. These plans outline the steps the applicant will take, such as garbage disposal, attractant management, and snow management procedures, to minimize impacts to polar bears by reducing the attraction of Industry activities to polar bears. Interaction plans also outline the chain of command for responding to a polar bear sighting.

4. Effect on Prey Species

Ringed seals are the primary prey of polar bears and bearded seals are a secondary prey source. Both species are managed by the NMFS, which will evaluate the potential impacts of oil and gas exploration activities in the Chukchi Sea through their appropriate authorization process and will identify appropriate mitigation measures for those species, if a negligible impact finding is appropriate. Industry would mainly have an effect on seals through the potential for industrial noise disturbance and contamination (oil spills). The Service does not expect prey availability to be significantly changed due to Industry activities. Mitigation measures for pinnipeds required by BOEM and NMFS will reduce the impact of Industry activities on ringed and bearded seals. A detailed description of potential Industry effects on pinnipeds in the Chukchi Sea can be found in the NMFS biological opinion, ''*Endangered Species Act—Section 7 Consultation, Biological Opinion; Issuance of Incidental Harassment Authorization under section 101(a)(5)(a) of the Marine Mammal Protection Act to Shell Offshore, Inc. for Exploratory Drilling in the Alaskan Chukchi Sea in 2012*'' (*http://www.nmfs.noaa.gov/pr/pdfs/permits/shell_chukchi_opinion.pdf*).

5. Polar Bear Habitat

Industry activities could also have potential impacts to polar bear habitat, which in some cases could lead to impacts to bears. The Service analyzed the effects of Industry activities on three habitat types important for polar bears. These are: (1) Sea ice, used for feeding, breeding, denning, and movements; (2) barrier island habitat, used for denning, refuge from human disturbance, and transit corridors; and (3) terrestrial denning habitat for denning. Industry activities may affect these described habitats as discussed below.

A. Sea Ice Habitat

The regulations only allow exploratory oil and gas activities to occur during the open-water season. However, support activities can occur throughout the year and may interact with sea ice habitat on a limited basis. Ice reconnaissance flights to survey ice characteristics and ice management operations using vessels to deflect ice floes from drill rigs are two types of activities that have the potential to affect sea ice. Support activities outside of the open-water season will be limited in scope and would likely have limited effects on sea ice habitat during the ice-covered seasons within the timeframe of these final regulations (2013 to 2018).

B. Barrier Island Habitat

Proposed support activities near communities, such as Wainwright and Point Lay, for seismic, shallow hazard surveys; open-water marine survey; or terrestrial environmental studies are the types of exploration activities requested that may affect polar bear barrier island habitat. Vessels associated with marine activities operating in the Chukchi Sea may use barrier island habitat to ''wait out a storm.'' Bears using the islands to rest and travel may encounter temporarily beached vessels. Past observations reported to the Service indicate that bears will walk by such vessels, but may not rest near them. This is a temporary effect associated with the beached vessel, and once the vessel is removed from the beach, the bears return to travelling or resting on the beach.

Aerial transport activities in support of Industry programs may also encounter barrier island habitat while transiting to and from communities. Air operations will have regulatory flight restrictions, but in certain circumstances, such as emergencies, flights could displace bears from barrier island habitat. Established mitigation measures described in these final regulations, such as minimum altitude restrictions, wildlife observers and adherence to company polar bear interaction plans, will further limit potential disturbances.

C. Terrestrial Denning Habitat

In western Alaska, mainland support facilities for offshore activities may occur within coastal polar bear habitat. Staging activities, remote camps, construction of ice roads, and aerial transport to support projects all have the potential to occur in coastal areas in or near denning habitat. If necessary, proactive and reactive mitigation measures set forth in these final regulations will minimize disturbance impacts to denning habitat. The Service may require den detection surveys in areas of denning habitat. At times, Industry may have to place ice roads or staging activities in coastal denning areas. Mitigation measures to minimize potential impacts include establishment of the 1-mile exclusion zone around known maternal dens, and the reduction of activity levels until the natural departure of the bears. Currently, what little is known about the denning habits of the Chukchi-Bering Sea population suggests that the majority of maternal dens occur in the Russian Federation, predominantly on Wrangel Island (DeBruyn *et al.* 2010). While denning habitat exists in western Alaska, few confirmed polar bear dens have been recorded in western Alaska since 2006 (Durner *et al.* 2010). A more detailed description of den detection techniques required by the Service and employed by exploration activities to limit disturbance and minimize impacts to maternal polar bear den sites has been discussed in the Service's Beaufort Sea regulations (76 FR 47010; August 3, 2011). The Service will implement these techniques if active polar bear dens are recorded during Industry activities.

Although Industry activities may temporarily reduce site-specific availability of small portions of polar bear habitat for feeding, mating, movements, denning, and access to prey, these actions will be temporary and not result in long-term effects on the habitat's capabilities to support biological functions of polar bears. Based on the information provided by the petitioners, the Service concludes that effects from Industry activity on polar bear habitat will be insignificant, due to the limited magnitude and the temporary nature of the activities.

Evaluation of Anticipated Effects on Polar Bears

The Service anticipates that potential impacts of seismic noise, physical obstructions, human encounters, changes in distribution or numbers of prey species in the offshore and onshore environments on polar bears will be limited to short-term changes in behavior that will have no long-term impact on individuals or identifiable impacts to the polar bear population during the 5-year timeframe of these regulations. Individual polar bears may be observed in the open water during offshore activities in Alaska waters, but the vast majority of the bear populations will be found on the pack ice or along the Chukotka coastline in the Russian Federation during this time of year. Onshore encounters with polar bears are expected to be minimal due to the limited activity planned along the coastline of Alaska during the timeframe of the regulations. We do not anticipate any lethal take due to Industry activities during the 5-year time period of these regulations. We expect that specific mitigation measures, such as education of Industry personnel, will minimize bear-human interactions that could lead to lethal take of polar bears. Our experience in the Beaufort Sea similarly suggests that it is unlikely there will be any lethal take of bears due to Industry activity within the 5-year time period of these regulations.

Potential impacts to bears will be mitigated through various requirements stipulated within LOAs. Mitigation measures that will be required for all projects include a polar bear interaction plan and a record of communication with affected villages that may serve as the precursor to a POC with the village to mitigate effects of the project on subsistence activities. Examples of mitigation measures that will be used on a case-by-case basis include: The use of trained marine mammal observers associated with offshore activities; bear monitors for onshore activities; and seismic shutdown procedures in ensonification zones. The Service implements an adaptive management approach where certain mitigation measures are based on need and effectiveness for specific activities based largely on timing and location. For example, the Service will implement different mitigation measures for an onshore baseline study 20 miles inland, than for an offshore drilling project. Based on past monitoring information, bears are more prevalent in the coastal areas than 20 miles inland. Therefore, the monitoring and mitigation measures that the Service deems appropriate must be implemented to limit the disturbance to bears, and the measures deemed necessary to limit bear-human interactions may differ depending on location and the timing of the activity.

Furthermore, mitigation measures imposed through BOEM/BSEE lease stipulations are designed to avoid Level A harassment (injury), reduce Level B harassment, reduce the potential for population level significant adverse effects on polar bears, and avoid an unmitigable adverse impact on their availability for subsistence purposes. Additional measures described in the these ITRs help reduce the level of Industry impacts to polar bears during the exploration activities, and the issuance of LOAs with site specific operating restrictions and monitoring requirements provide mitigation and protection for polar bears. Therefore, we conclude that the exploration activities, as mitigated through the regulatory process, will only impact small numbers of animals, are not expected to have more than negligible impacts on polar bears in the Chukchi Sea, and will not have an unmitigable, adverse impact on the availability of polar bears for subsistence uses.

Potential Impacts of Waste Product Discharge and Oil Spills on Pacific Walruses and Polar Bears

In this section, we discuss the potential effects of oil spills from Industry activities on Pacific walruses and polar bears. We recognize that a wide range of potential effects from oil spills on these species could occur, from minimal effects to potentially substantial ones. We emphasize, however, that the only types of spills that could have significant effects on these species are large spills. Based on projections from BOEM/BSEE, the likelihood of large spills from Industry exploration activities are extremely remote, and thus, we consider impacts from such spills to be highly unlikely. Nevertheless, we provide a full discussion of oil spill risks and possible effects from oil spills, in the extremely unlikely event that such a spill could occur.

Effects of Waste Discharge and Potential Oil Spills on Pacific Walrus

The possibility of oil and waste product spills from Industry exploration activities and the subsequent impacts on walruses are a concern. Little is known about the effects of either on walruses as no studies have been conducted and no documented spills have occurred affecting walruses in their habitat. Depending on the extent of an oil spill, adult walruses may not be severely affected through direct contact, but they will be extremely sensitive to any disturbances created by spill response activities. In addition, due to the gregarious nature of walruses, a release of contaminants will most likely affect multiple individuals if it occurred in an area occupied by walruses. Walruses may repeatedly expose themselves to waste or oil that has accumulated at the

edge of a shoreline or ice lead as they enter and exit the water.

Damage to the skin of pinnipeds can occur from contact with oil because some of the oil penetrates into the skin, causing inflammation and death of some tissue. The dead tissue is discarded, leaving behind an ulcer. While these skin lesions have only rarely been found on oiled seals, the effects on walruses may be greater because of a lack of hair to protect the skin. Like other pinnipeds, walruses are susceptible to oil contamination in their eyes. Direct exposure to oil could also result in conjunctivitis. Continuous exposure to oil would quickly cause permanent eye damage.

Inhalation of hydrocarbon fumes presents another threat to marine mammals. In studies conducted on pinnipeds, pulmonary hemorrhage, inflammation, congestion, and nerve damage resulted after exposure to concentrated hydrocarbon fumes for a period of 24 hours. If the walruses were also under stress from molting, pregnancy, etc., the increased heart rate associated with the stress would circulate the hydrocarbons more quickly, lowering the tolerance threshold for ingestion or inhalation.

Adult and sub-adult walruses have thick skin and blubber layers for insulation and very little hair. Thus, they exhibit no grooming behavior, which lessens their chance of ingesting oil. Heat loss is regulated by control of peripheral blood flow through the animal's skin and blubber. Direct exposure of adult walruses to oil is not believed to have any effect on the insulating capacity of their skin and blubber, although it is unknown if oil could affect their peripheral blood flow.

Walrus calves are also likely to suffer from the effects of oil contamination. Walrus calves can swim almost immediately after birth and will often join their mother in the water, increasing their risk of being oiled. However, calves have not yet developed enough insulating blubber to spend as much time in the water as adults. It is possible that oiled walrus calves may not be able to regulate heat loss and may be more susceptible to hypothermia. Another possibility is an oiled calf that is unable to swim away from the contamination and a cow that would not leave without the calf, resulting in the potential exposure of both animals. However, it is also possible that an oiled calf would be unrecognizable to its mother either by sight or by smell, and be abandoned.

Walruses are benthic feeders, and the fate of benthic prey contaminated by an oil spill is difficult to predict. In general, benthic invertebrates preferred by walruses (bivalves, gastropods, and polychaetes) may either decline or increase as the result of a spill (Sanders *et al.* 1980; Jacobs 1980; Elmgren *et al.* 1983; Jewett *et al.* 1999). Impacts vary among spills and species within a spill, but in general, benthic communities move through several successive stages of temporal change until the communities approach pre-disturbance conditions (Dauvin 1998), which may take 20 years. Much of the benthic prey contaminated by an oil spill or gas release, such as methane, may be killed immediately. Bivalve mollusks, a favorite prey species of the walrus, are not effective at processing hydrocarbon compounds, resulting in highly concentrated accumulations and long-term retention of the contamination within the organism. In addition, because walruses feed primarily on mollusks, they may be highly vulnerable to a loss of this prey species. However, epifaunal bivalves were one of the benthic community classes that increased following the *Exxon Valdez* spill in Alaska (Jewett *et al.* 1999).

Depending on the location and timing, oil spills could affect walruses in a number of ways. An offshore spill during open water may only affect a few walruses swimming through the affected area. However, spilled oil present along ice edges and ice leads in fall or spring during formation or breakup of ice presents a greater risk because of both the difficulties associated with cleaning oil in mixed, broken ice, and the presence of wildlife in prime feeding areas over the continental shelf during this period. Oil spills affecting areas where walruses and polar bears are concentrated, such as along off-shore leads, polynyas, preferred feeding areas, and terrestrial habitat used for denning or haulouts would affect more animals than spills in other areas.

The potential impacts to Pacific walruses from a spill could be significant, particularly if subsequent cleanup efforts are ineffective. These potential impacts would be greatest when walruses are aggregated at coastal haulouts. For example, walruses would be most vulnerable to the effects of an oil spill at coastal haulouts if the oil comes within 60 km of the coast (Garlich-Miller *et al.* 2010, p. 87). Spilled oil during the ice-covered season not cleaned up could become part of the ice substrate and be eventually released back into the environment during the following open-water season. During spring melt, oil would be collected by spill response activities, but it could eventually contact a limited number of walruses.

In the unlikely event there is an oil spill and walruses are in the same area, mitigation measures, especially those to deflect and deter animals from spilled areas, may minimize the associated risks. Fueling crews have personnel that are trained to handle operational spills and contain them. If a small offshore spill occurs, spill response vessels are stationed in close proximity and are required to respond immediately. A detailed discussion of oil spill prevention and response for walruses can be found at the following Web site: *http://www.fws.gov/Contaminants/FWS_OSCP_05/FWSContingency TOC.htm.*

Although fuel and oil spills have the potential to cause adverse impacts to walruses and possibly some prey species, operational spills associated with the exploration activities are not considered a major threat. Operational spills would likely be of a relatively small volume, and occur in areas of open water where walrus densities are expected to be low. Furthermore, blowout prevention technology will be required for all exploratory drilling operations in the Chukchi Sea by the permitting agencies, and the BOEM/BSEE considers the likelihood of a blowout occurring during exploratory drilling in the Chukchi Sea as negligible (OCS EIS/EA MMS 2007–026). The BOEM/BSEE operating stipulations, including oil spill prevention and response plans, reduce both the risk and scale of potential spills. For these reasons, any impacts associated with an operational spill are expected to be limited to a small number of animals.

Effects of Waste Discharge and Potential Oil Spills on Polar Bear

Individual polar bears can potentially be affected by Industry activities through waste product discharge and oil spills. In 1980, Canadian scientists performed experiments that studied the effects to polar bears of exposure to oil. Effects on experimentally oiled polar bears (where bears were forced to remain in oil for prolonged periods) included acute inflammation of the nasal passages, marked epidermal responses, anemia, anorexia, and biochemical changes indicative of stress, renal impairment, and death. Many effects did not become evident until several weeks after the experiment (Øritsland *et al.* 1981).

Oiling of the pelt causes significant thermoregulatory problems by reducing the insulation value. Irritation or damage to the skin by oil may further contribute to impaired thermoregulation. Experiments on live polar bears and pelts showed that the

thermal value of the fur decreased significantly after oiling, and oiled bears showed increased metabolic rates and elevated skin temperature. Oiled bears are also likely to ingest oil as they groom to restore the insulation value of the oiled fur.

Oil ingestion by polar bears through consumption of contaminated prey, and by grooming or nursing, could have pathological effects, depending on the amount of oil ingested and the individual's physiological state. Death could occur if a large amount of oil is ingested or if volatile components of oil were aspirated into the lungs. Indeed, two of three bears died in the Canadian experiment, and it was suspected that the ingestion of oil was a contributing factor to the deaths. Experimentally oiled bears ingested much oil through grooming. Much of it was eliminated by vomiting and in the feces; some was absorbed and later found in body fluids and tissues.

Ingestion of sub-lethal amounts of oil can have various physiological effects on a polar bear, depending on whether the animal is able to excrete or detoxify the hydrocarbons. Petroleum hydrocarbons irritate or destroy epithelial cells lining the stomach and intestine, thereby affecting motility, digestion, and absorption.

Polar bears swimming in, or walking adjacent to, an oil spill could inhale petroleum vapors. Vapor inhalation by polar bears could result in damage to various systems, such as the respiratory and the central nervous systems, depending on the amount of exposure.

Oil may also affect food sources of polar bears. Seals that die because of an oil spill could be scavenged by polar bears. This would increase exposure of the bears to hydrocarbons and could result in lethal impact or reduced survival to individual bears. A local reduction in ringed seal numbers because of direct or indirect effects of oil could temporarily affect the local distribution of polar bears. A reduction in density of seals as a direct result of mortality from contact with spilled oil could result in polar bears not using a particular area for hunting. Possible impacts from the loss of a food source could reduce recruitment and/or survival.

The persistence of toxic subsurface oil and chronic exposures, even at sub-lethal levels, can have long-term effects on wildlife (Peterson *et al.* 2003). Although it may be true that small numbers of bears may be affected by an oil spill initially, the long-term impact could be much greater. Long-term oil effects could be substantial through interactions between natural environmental stressors and compromised health of exposed animals, and through chronic, toxic exposure because of bioaccumulation. Polar bears are biological sinks for pollutants because they are the apical predator of the Arctic ecosystem and are opportunistic scavengers of other marine mammals. Additionally, their diet is composed mostly of high-fat sealskin and blubber (Norstrom *et al.* 1988). The highest concentrations of persistent organic pollutants in Arctic marine mammals have been found in polar bears and seal-eating walruses near Svalbard (Norstrom *et al.* 1988; Andersen *et al.* 2001; Muir *et al.* 1999). As such, polar bears would be susceptible to the effects of bioaccumulation of contaminants associated with spilled oil, which could affect the bears' reproduction, survival, and immune systems. Sub-lethal, chronic effects of any oil spill may further suppress the recovery of polar bear populations due to reduced fitness of surviving animals.

In addition, subadult polar bears are more vulnerable than adults are to environmental effects (Taylor *et al.* 1987). Subadult polar bears would be most prone to the lethal and sub-lethal effects of an oil spill due to their proclivity for scavenging (thus increasing their exposure to oiled marine mammals) and their inexperience in hunting. Indeed, grizzly bear researchers in Katmai National Park suspected that oil ingestion contributed to the death of two yearling grizzly bears in 1989, after the *Exxon Valdez* oil spill. They detected levels of naphthalene and phenathrene in the bile of one of the bears. Because of the greater maternal investment a weaned subadult represents, reduced survival rates of subadult polar bears have a greater impact on population growth rate and sustainable harvest than reduced litter production rates (Taylor *et al.* 1987).

During the open-water season (July to October), bears in the open water or on land may encounter and be affected by any such oil spill; however, given the seasonal nature of the Industry activities, the potential for direct negative impacts to polar bears would be minimized. During the ice-covered season (November to May), onshore Industry activities will have the greatest likelihood of exposing transiting polar bears to potential oil spills. Although the majority of the Chukchi Sea polar bear population spends a large amount of time offshore on the annual or multi-year pack ice and along the Chukotka coastline, some bears could encounter oil from a spill regardless of the season and location.

Small spills of oil or waste products throughout the year by Industry activities on land could potentially affect small numbers of bears. The effects of fouling fur or ingesting oil or wastes, depending on the amount of oil or wastes involved, could be short-term or result in death. For example, in April 1988, a dead polar bear was found on Leavitt Island, in the Beaufort Sea, approximately 9.3 km (5 nautical miles) northeast of Oliktok Point. The cause of death was determined to be poisoning by a mixture that included ethylene glycol and Rhodamine B dye. While industrial in origin, the source of the mixture was unknown.

The major concern regarding large oil spills is the impact a spill would have on the survival and recruitment of the Chukchi Sea and southern Beaufort Sea polar bear populations that use the region. Currently, the Southern Beaufort Seas bear population is approximately 1,500 bears, and the Chukchi Sea bear population estimate is 2,000.

These populations may be able to sustain the additional mortality caused by a large oil spill if a small number of bears are killed; however, the additive effect of numerous bear deaths due to the direct or indirect effects from a large oil spill are more likely to reduce population recruitment and survival. Indirect effects may occur through a local reduction in seal productivity or scavenging of oiled seal carcasses and other potential impacts, both natural and human-induced. The removal of a large number of bears from either population would exceed sustainable levels, potentially causing a decline in bear populations and affecting bear productivity and subsistence use.

The time of greatest impact from an oil spill to polar bears is most likely during the ice-covered season when bears use the ice. To access ringed and bearded seals, polar bears concentrate in shallow waters less that 300 m deep over the continental shelf and in areas with greater than 50 percent ice cover (Durner *et al.* 2004). At this time, bears may be exposed to any remnant oil from the previous open-water season. Spilled oil also can concentrate and accumulate in leads and openings that occur during spring break-up and autumn freeze-up periods. Such a concentration of spilled oil would increase the chance that polar bears and their principal prey would be oiled.

Potential impacts of Industry waste products and oil spills suggest that individual bears could be impacted by this type of disturbance were it to occur. Depending on the amount of oil or

wastes involved, and the timing and location of a spill, impacts could be short-term, chronic, or lethal. In order for bear population reproduction or survival to be impacted, a large-volume oil spill would have to take place. According to BOEM/BSEE, during exploratory activities, the probability of a large oil spill (defined as ≥ 1,000 barrels [bbls]) occurring throughout the duration of these regulations (5 years) is very small. In addition, protocols for controlling waste products in project permits will limit exposure of bears to the waste products. Current management practices by Industry, such as requiring the proper use, storage, and disposal of hazardous materials, minimize the potential occurrence of such incidents. In the event of an oil spill, it is also likely that polar bears would be intentionally hazed to keep them away from the area, further reducing the likelihood of affecting the population. Oil spill contingency plans are authorized by project permitting agencies and, if necessary, would limit the exposure of bears to oil.

Description of Waste Product Discharge and Oil Spills

Waste products are substances that can be accidently introduced into the environment by Industry activities. Examples include ethyl glycol, drilling muds, or treated water. Generally, they are released in small amounts. Oil spills are releases of oil or petroleum products. In accordance with the National Pollutant Discharge Elimination System Permit Program, all oil companies must submit an oil spill contingency plan with their projects. It is illegal to discharge oil into the environment, and a reporting system requires operators to report even small spills. BOEM/BSEE classifies oil spills as either small (< 1,000 bbls) or large (≥ 1,000 bbls). A volume of oil of 1,000 bbls equals 42,000 U.S. gallons (gal), or 158,987 liters (L). Reported small spills are those that have occurred during standard Industry operations. Examples include oil, gas, or hydraulic fluid spills from mechanized equipment or spills from pipelines or facilities. While oil spills are unplanned events, large spills are associated with oil platforms, such as drill rigs or pads and pipelines. There is generally some form of human error combined with faulty equipment, such as pipeline degradation, that causes a large spill.

Most regional oil spill information comes from the Beaufort Sea area, where oil and gas production has already been established. BOEM's most current data suggest that between 1977 and 1999, an average of 70 oil and 234 waste product spills occurred annually on the North Slope oil fields in the terrestrial and marine environment. Although most spills have been small (less than 50 bbls, 2,100 gal, or 7,950 L) by Industry standards, larger spills accounted for much of the annual volume. Historically, Industry has had 35 small spills totaling 26.7 bbls (1,121 gal, 4,245 L) in the OCS. Of the 26.7 bbls spilled, approximately 24 bbls (1,008 gal, 3,816 L) were recovered or cleaned up. Seven large, terrestrial oil spills occurred between 1985 and 2009 on the Beaufort Sea North Slope. The largest oil spill occurred in the spring of 2006, where approximately 5,714 bbls (260,000 gal, 908,500 L) leaked from flow lines near a gathering center. In November 2009, a 1,095 bbls (46,000 gal, 174,129 L) oil spill occurred as well. Both of these spills occurred at production sites. More recently, in 2012, a gas blowout occurred at an exploration well on the Colville River Delta where approximately 1,000 bbls (42,000 gal, 159,987 L) of drilling mud and an unknown amount of natural gas was expelled. These spills were terrestrial and posed minimal threat to polar bears and walruses.

For exploratory operations, according to BOEM/BSEE, Industry has drilled 35 offshore exploratory wells, five of which occurred in the Chukchi Sea prior to 1992. To date, no major exploratory offshore-related oil spills have occurred on the North Slope in either the Beaufort or Chukchi seas.

Historical large spills (≥ 1,000 bbls, 42,000 gal, or 159,987 L) associated with Alaskan oil and gas activities on the North Slope have been production-related, and have occurred at production facilities or pipelines connecting wells to the Trans-Alaska Pipeline System. The BOEM/BSEE estimates the chance of a large (≥ 1,000 bbls, 42,000 gal, or 159,987 L) oil spill from exploratory activities in the Chukchi Sea to be low based on the types of spills recorded in the Beaufort Sea. The greatest risk potential for oil spills from exploration activities likely occurs with the marine vessels. From past experiences, BOEM/BSEE believes these would most likely be localized and relatively small. Spills in the offshore or onshore environments classified as small could occur during normal operations (e.g., transfer of fuel, handling of lubricants and liquid products, and general maintenance of equipment). The likelihood of small spills occurring is higher than large spills. However, because small spills would likely be contained and remediated quickly, their potential impacts on walruses and polar bears are expected to be low. There is a greater potential for large spills in the Chukchi Sea region from drilling platforms. Exploratory drilling platforms are required to have containment ability in case of a blowout as part of their oil spill contingency plans, where the likelihood of a large release during the 5-year timeframe of these regulations remains minimal.

Our analysis of oil and gas development potential and subsequent risks was based on the BOEM/BSEE analysis that they conducted for the Chukchi Sea lease sale (MMS 2007 and BOEMRE 2011), which is the best available information. Due to the *Deepwater Horizon* (DWH) incident in the Gulf of Mexico, offshore oil and gas activities are under increased scrutiny. As such, BOEM/BSEE developed a very large oil spill analysis (BOEMRE 2011–041; *http://www.boem.gov/uploadedFiles/BOEM/About_BOEM/BOEM_Regions/Alaska_Region/Environment/Environmental_Analysis/2011-041v1.pdf*), where the potential impacts of a very large oil spill to polar bears and Pacific walruses are described (sections IV.E.8 and IV.E.11, respectively).

Of the potential impacts to Pacific walruses and polar bears from Industry activity in the Chukchi Sea, the impacts from a very large oil spill is of the most concern during the duration of these regulations. Though not part of standard operating conditions, we have addressed the analysis of a very large oil spill due to the potential that a spill of this magnitude could significantly impact Pacific walruses and polar bears. During the next 5 years, offshore exploratory drilling would be the predominant source of a very large oil spill in the unlikely event one occurred.

Multiple factors have been examined to compare and contrast an oil spill in the Arctic to that of *Deepwater Horizon.* In the event of a spill in the Chukchi Sea, factors that could limit the impact of a spill could include the drilling depth and the well pressures. The *Deepwater Horizon* blowout occurred in 5,000 ft (1,524 m) of water with well pressures of approximately 15,000 psi (approximately 103,421 kPa). (Schmidt 2012). The Chukchi Sea sites are calculated to have drilling depths of approximately 150 ft (46 m) and well pressures not to exceed 3,000 to 4,000 psi (approximately 20,684 to 27,579 kPa). With lower drilling depths and well pressures, well sites in the Chukchi Sea will be more accessible in the event of a spill. However, spill response and cleanup of an oil spill in the Arctic has not been fully vetted to the point where major concerns no longer remain.

The BOEM/BSEE has acknowledged difficulties in effectively responding to oil spills in broken ice conditions, and The National Academy of Sciences has determined that ''no current cleanup methods remove more than a small fraction of oil spilled in marine waters, especially in the presence of broken ice'' (NRC 2003). Current oil spill responses in the Chukchi Sea include three main response mechanisms, blowout prevention, *in-situ* burning, and chemical dispersants *(http://www.bsee.gov/OSRP/Shell-Chukchi-OSRP.aspx*). Each response has associated strengths and weaknesses, where the success would be mostly dependent on weather conditions. The BOEM/BSEE advocates the use of non-mechanical methods of spill response, such as *in-situ* burning, during periods when broken ice would hamper an effective mechanical response (MMS 2008). An *in-situ* burn has the potential to rapidly remove large quantities of oil and can be employed when broken-ice conditions may preclude mechanical response. However, oil spill cleanup in the broken ice and open water conditions that characterize Arctic waters continues to be problematic.

In addition to the BOEM/BSEE analysis (BOEMRE 2011), policy and management changes have occurred within the Department of the Interior that are designed to increase the effectiveness of oversight activities and further reduce the probability and effects of an accidental oil spill (USDOI 2010). As a result, based on projections from BOEM/BSEE, we anticipate that the potential for a significant oil spill will remain low at the exploration stage; however, we recognize that should a large spill occur, effective strategies for oil spill cleanup in the broken ice and open-water conditions that characterize walrus and polar bear habitat in the Chukchi Sea are limited.

In the event of a large oil spill, Service-approved response strategies are in place to reduce the impact of a spill on walrus and polar bear populations. Service response efforts will be conducted under a 3-tier approach characterized as: (1) Primary response, involving containment, dispersion, burning, or cleanup of oil; (2) secondary response, involving hazing, herding, preventative capture/relocation, or additional methods to remove or deter wildlife from affected or potentially affected areas; and (3) tertiary response, involving capture, cleaning, treatment, and release of wildlife. If the decision is made to conduct response activities, primary and secondary response options will be most applicable, as little evidence exists that tertiary methods will be effective for cleaning oiled walruses or polar bears.

In 2012, the Service and representatives from oil companies operating in the Arctic conducted tests on polar bear fur to evaluate appropriate oil cleaning techniques specific to oil grades extracted from local Alaskan oil fields. The analysis is ongoing and will be reported in the future. In addition, capturing and handling of adult walruses is difficult and risky, as walruses do not react well to anesthesia, and calves have little probability of survival in the wild following capture and rehabilitation. In addition, many Alaska Native organizations are opposed to releasing rehabilitated marine mammals into the wild due to the potential for disease transmission.

All Industry projects will have project specific oil spill contingency plans that will be approved by the appropriate permitting agencies prior to the issuance of an LOA. The contingency plans have a wildlife component, which outlines protocols to minimize wildlife exposure, including exposure of polar bears and walruses, to oil spills. Operators in the OCS are advised to review the Service's *Oil Spill Response Plan for Polar Bears in Alaska* and the Pacific Walrus Response Plan at *http://www.fws.gov/Contaminants/FWS_OSCP_05/FWSContingencyTOC.htm* when developing spill-response tactics. Multiple factors will be considered when responding to an oil spill, including: the location of the spill; the magnitude of the spill; oil viscosity and thickness; accessibility to spill site; spill trajectory; time of year; weather conditions (i.e., wind, temperature, precipitation); environmental conditions (i.e., presence and thickness of ice); number, age, and sex of walruses and polar bears that are (or are likely to be) affected; degree of contact; importance of affected habitat; cleanup proposal; and likelihood of animal-human interactions.

As discussed above, large oil spills from Industry activities in the Chukchi and Beaufort seas and coastal regions that would impact walruses and polar bears have not yet occurred, although the exploration of oil and gas has increased the potential for large offshore oil spills. With limited background information available regarding the effects of potential oil spills on the Arctic environment, the outcome of such a spill is uncertain. For example, the extent of impacts of a large oil spill as well as the types of equipment needed and potential for effective cleanup would be greatly influenced by seasonal weather and sea conditions, including temperature, winds, wave action, and currents. Based on the experiences of cleanup efforts following the *Deepwater Horizon* and *Exxon Valdez* oil spills, where logistical support was readily available and wildlife resources were nevertheless affected, spill response may be largely unsuccessful in open-water conditions. Arctic conditions and the remoteness of exploration activities would greatly complicate any spill response.

While it is extremely unlikely that a significant amount of oil would be discharged into the environment by an exploratory program during the regulatory period, the Service is aware of the risk that hydrocarbon exploration entails and that a large spill could occur in the development and production of oil fields in the future, where multiple operations incorporating pads and pipelines would increase the possibility of oil spills and impacts to walruses and polar bears. The Service will continue to work to minimize impacts to walruses and polar bears from Industry activities, including reducing impacts of oil spills.

Potential Effects of Oil and Gas Industry Activities on Subsistence Uses of Pacific Walruses and Polar Bears

The open-water season for oil and gas exploration activities coincides with peak walrus hunting activities in the Chukchi Sea region. The subsistence harvest of polar bears can occur year-round in the Chukchi Sea, depending on ice conditions, with peaks usually occurring in spring and fall. Effects to subsistence harvests will be addressed in Industry POCs. The POCs are discussed in detail later in this section.

Noise and disturbances associated with oil and gas exploration activities have the potential to adversely impact subsistence harvests of walruses and polar bears by displacing animals beyond the hunting range (60 to 100 mi [96.5 to 161 km] from the coast) of these communities. Disturbances associated with exploration activities could also heighten the sensitivity of animals to humans with potential impacts to hunting success. Little information is available to predict the effects of exploration activities on the subsistence harvest of walruses and polar bears. Hunting success varies considerably from year to year because of variable ice and weather conditions. Changing walrus distributions due to declining sea ice and accelerated sea ice melt are currently affecting hunting opportunities.

Measures to mitigate potential effects of oil and gas exploration activities on marine mammal resources and subsistence use of those resources were

identified and developed through previous BOEM/BSEE Lease Sale National Environmental Policy Act (NEPA) (42 U.S.C. 4321 et seq.) review and analysis processes. The Final Lease Stipulations for the Oil and Gas Lease Sale 193 in the Chukchi Sea identify several existing measures designed to mitigate potential effects of oil and gas exploration activities on marine mammal resources and subsistence use of those resources (*http://www.boem.gov/uploadedFiles/BOEM/Oil_and_Gas_Energy_Program/Leasing/Regional_Leasing/Alaska_Region/Alaska_Lease_Sales/Sale_193/Stips.pdf*).

Seven lease stipulations were selected by the Secretary of the Interior in the Final Notice of Sale for Lease 193. These are: Stipulation (1) Protection of Biological Resources; Stipulation (2) Orientation Program; Stipulation (3) Transportation of Hydrocarbons; Stipulation (4) Industry Site Specific Monitoring Program for Marine Mammal Subsistence Resources; Stipulation (5) Conflict Avoidance Mechanisms to Protect Subsistence Whaling and Other Marine Mammal Subsistence Harvesting Activities; Stipulation (6) Pre-Booming Requirements for Fuel Transfers; and Stipulation (7) Measures to Minimize Effects to Spectacled and Steller's Eiders during Exploration Activities.

Lease stipulations that directly support minimizing impacts to walruses, polar bears and the subsistence use of those animals include Stipulations 1, 2, 4, 5, 6, and 7. Stipulation 1 allows BOEM/BSEE to require the lessee to conduct biological surveys for previously unidentified biological populations or habitats to determine the extent and composition of the population or habitat. Stipulation 2 requires that an orientation program be developed by the lessee to inform individuals working on the project of the importance of environmental, social, and cultural resources, including how to avoid disturbing marine mammals and endangered species. Stipulation 4 provides for site-specific monitoring programs, which will provide information about the seasonal distributions of walruses and polar bears. The information can be used to improve evaluations of the threat of harm to the species and provides immediate information about their activities, and their response to specific events, where this stipulation applies specifically to the communities of Barrow, Wainwright, Point Lay, and Point Hope. This stipulation is expected to reduce the potential effects of exploration activities on walruses, polar bears, and the subsistence use of these resources. This stipulation also contributes important information to ongoing walrus and polar bear research and monitoring efforts.

Stipulation 5 will help reduce potential conflicts between subsistence hunters and proposed oil and gas exploration activities. This stipulation is meant to help reduce noise and disturbance conflicts from oil and gas operations during specific periods, such as peak hunting seasons. It requires that the lessee meet with local communities and subsistence groups to resolve potential conflicts. The consultations required by this stipulation ensure that the lessee, including contractors, consult and coordinate both the timing and sighting of events with subsistence users. The intent of these consultations is to identify any potential conflicts between proposed exploration activities and subsistence hunting opportunities in the coastal communities. Where potential conflicts are identified, BOEM/BSEE may require additional mitigation measures as identified by NMFS and the Service through MMPA authorizations. Stipulation 6 will limit the potential of fuel spill into the environment by requiring the fuel barge to be surrounded by an oil spill containment boom during fuel transfer.

While Stipulation 7 is intended to minimize effects to spectacled and Steller's eiders during exploration activities, Condition a2b of Stipulation 7 addresses vessel traffic in the Ledyard Bay Critical Habitat Area and imposes vessel traffic restrictions in this area between July 1 to November 15. These restrictions will also help minimize impacts to walruses, where the Ledyard Bay Critical Habitat Area and the high use areas of Pacific walruses overlap, for example along the barrier islands and surrounding waters of the Point Lay haulout.

The BOEM/BSEE lease sale stipulations and mitigation measures will be applied to all exploration activities in the Chukchi Lease Sale Planning Area and the geographic region of the ITRs. The Service has incorporated these BOEM/BSEE lease sale stipulations into its analysis of impacts to walruses and polar bears in the Chukchi Sea.

In addition to the existing BOEM/BSEE Final Lease Stipulations described above, the Service has also developed additional mitigation measures that will be implemented through these ITRs. These stipulations are currently in place under our regulations published on June 11, 2008 (73 FR 33212), and will also apply for these final regulations. The following LOA stipulations, which will mitigate potential impacts to subsistence walrus and polar bear hunting from the activities, apply to all incidental take authorizations:

(1) Prior to receipt of an LOA, applicants must contact and consult with the communities of Point Hope, Point Lay, Wainwright, and Barrow through their local government organizations to identify any additional measures to be taken to minimize adverse impacts to subsistence hunters in these communities. A POC will be developed if there is a general concern from the community that the activities will impact subsistence uses of walruses or polar bears. The POC must address how applicants will work with the affected Native communities and what actions will be taken to avoid interference with subsistence hunting of walruses and polar bears. The Service will review the POC prior to issuance of the LOA to ensure that applicants adequately address any concerns raised by affected Native communities such that any potential adverse effects on the availability of the animals are minimized.

(2) Authorization will not be issued by the Service for the take of polar bears and walruses associated with activities in the marine environment that occur within a 40-mile (64 km) radius of Barrow, Wainwright, Point Hope, or Point Lay, unless expressly authorized by these communities through consultations or through a POC. This condition is intended to limit potential interactions between Industry activities and subsistence hunting in near shore environments.

(3) Offshore exploration activities will be authorized only during the open-water season, which will not exceed the period of July 1 to November 30. This condition is intended to allow communities the opportunity to participate in subsistence hunts without interference and to minimize impacts to walruses during the spring migration. Variances to this operating condition may be issued by the Service on a case-by-case basis, based upon a review of seasonal ice conditions and available information on walrus and polar bear distributions in the area of interest.

(4) A 15-mile (24-km) separation must be maintained between all active seismic survey source vessels and/or drill rigs during exploration activities to mitigate cumulative impacts to resting, feeding, and migrating walruses. This does not include support vessels.

Plan of Cooperation (POC)

As a condition of incidental take authorization, and to ensure that Industry activities do not impact

subsistence opportunities for communities within the geographic region covered by these final regulations, any applicant requesting an LOA is required to present a record of communication that reflects discussions with the Alaska Native communities most likely affected by the activities. Prior to issuance of an LOA, Industry must provide evidence to the Service that an adequate POC has been coordinated with any affected subsistence community (or, as appropriate, with the EWC, the ANC, and the NSB) if, after community consultations, Industry and the community conclude that increased mitigation and monitoring is necessary to minimize impacts to subsistence resources. Where relevant, a POC will describe measures to be taken to mitigate potential conflicts between the Industry activity and subsistence hunting. If requested by Industry or the affected subsistence community, the Service will provide guidance on the development of the POC. The Service will review all POCs and will reject POCs that do not provide adequate safeguards to ensure that any taking by Industry will not have an unmitigable adverse impact on the availability of polar bears and walruses for taking for subsistence uses.

Included as part of the POC process and the overall State and Federal permitting process of Industry activities, Industry engages the Alaska Native communities in numerous informational meetings. During these community meetings, Industry must ascertain if community responses indicate that impact to subsistence uses will occur as a result of activities in the requested LOA. If community concerns suggest that Industry activities may have an impact on the subsistence uses of these species, the POC must provide the procedures on how Industry will work with the affected Native communities and what actions will be taken to avoid interfering with the availability of polar bears and walruses for subsistence harvest.

In making this finding, we considered the following: (1) Historical data regarding the timing and location of harvests; (2) effectiveness of mitigation measures stipulated by BOEM/BSEE-issued operational permits; (3) Service regulations proposed to be codified at 50 CFR 18.118 for obtaining an LOA, which include requirements for community consultations and POCs, as appropriate, between the applicants and affected Native communities; (4) effectiveness of mitigation measures stipulated by Service-issued LOAs; and (5) anticipated effects of the applicants' proposed activities on the distribution and abundance of walruses and polar bears. Based on the best scientific information available and the results of harvest data, including affected villages, the number of animals harvested, the season of the harvests, and the location of hunting areas, we find that the effects of the exploration activities in the Chukchi Sea region will not have an unmitigable adverse impact on the availability of walruses and polar bears for taking for subsistence uses during the 5-year timeframe of these regulations.

Analysis of Impacts of the Oil and Gas Industry on Pacific Walruses and Polar Bears in the Chukchi Sea

Pacific Walrus

Recent offshore activities in the Chukchi and Beaufort seas from the 1980s to the present highlight the type of documented impacts offshore activities can have on walruses. More oil and gas activity has occurred in the Beaufort Sea OCS than in the Chukchi Sea OCS. Many offshore activities required ice management, helicopter traffic, fixed wing aircraft monitoring, other support vessels, and stand-by barges. Although Industry has encountered walruses while conducting exploratory activities in the Beaufort and Chukchi seas, to date, no walruses are known to have been injured or killed due to encounters associated with Industry activities.

1. Reported Observations

Aerial surveys and vessel based observations of walruses were carried out in 1989 and 1990, to examine the responses of walruses to drilling operations at three Chukchi Sea drill prospects (Brueggeman *et al.* 1990, 1991). Aerial surveys documented several thousand walruses in the vicinity of the drilling prospects; most of the animals (> 90 percent) were closely associated with sea ice. The observations demonstrated that: (1) Walrus distributions were closely linked with pack ice; (2) pack ice was near active drill prospects for short time periods; and (3) ice passing near active prospects contained relatively few animals. Thus, the effects of the drilling operations on walruses were short-term, temporary, and in a discrete area near the drilling operations, and the portion of the walrus population affected was small.

Between 2006 and 2011, monitoring by Industry during seismic surveys in the Chukchi Sea resulted in 1,801 observed encounters involving approximately 11,125 individual walruses (Table 3). We classified the behavior of walruses associated with these encounters as: (1) No reaction; (2) attention (watched vessel); (3) approach (moved toward vessel); (4) avoidance (moved away from vessel at normal speed); (5) escape or flee (moved away from vessel at high rate of speed); and (6) unknown. These classifications were based on MMO on-site determinations or their detailed notes on walrus reactions that accompanied the observation. Data typically included the behavior of an animal or group when initially spotted by the MMO and any subsequent change in behavior associated with the approach and passing of the vessel. This monitoring protocol was designed to detect walruses far from the vessel and avoid and mitigate take, not to estimate the long-term impacts of the encounters on individual animals.

TABLE 3—SUMMARY OF PACIFIC WALRUS RESPONSES TO ENCOUNTERS WITH SEISMIC SURVEY VESSELS IN THE CHUKCHI SEA OIL AND GAS LEASE SALE AREA 193 IN 2006–2010 AS RECORDED BY ON-BOARD MARINE MAMMAL OBSERVERS

Walrus reaction	Number of encounters	Number of individuals	Mean (SE [a]) individuals/ encounter	Mean (SE) meters from vessel
None	955	7,310	8(1.7)	710(24)
Attention	285	1,419	5(1.9)	446(29)
Approach	47	89	2(0.3)	395(50)
Avoidance	435	940	2(0.1)	440(26)
Flee	47	170	4(0.9)	382(56)
Unknown	32	1,197	37(29.0)	558(78)

TABLE 3—SUMMARY OF PACIFIC WALRUS RESPONSES TO ENCOUNTERS WITH SEISMIC SURVEY VESSELS IN THE CHUKCHI SEA OIL AND GAS LEASE SALE AREA 193 IN 2006–2010 AS RECORDED BY ON-BOARD MARINE MAMMAL OBSERVERS—Continued

Walrus reaction	Number of encounters	Number of individuals	Mean (SE [a]) individuals/ encounter	Mean (SE) meters from vessel
Total or overall mean	1,801	11,125	6(1.1)	582(15)

[a] Standard error.

Nonetheless, the data do provide insight as to the short-term responses of walruses to vessel encounters.

Descriptive statistics were estimated based on both the number of encounters and number of individuals involved (Table 3). For both metrics (encounters and individuals), the most prevalent behavioral response was no response (53 and 66 percent, respectively) (Table 3); followed by attention or avoidance (8 and 24 percent combined, respectively), with the fewest animals exhibiting a flight response (3 and 2 percent, respectively). Based on these observation data, it is likely that relatively few animals were encountered during these operations each year (less than 2 percent of a minimum population of 129,000) and that of those encountered, walrus responses to vessel encounters were minimal. The most vigorous observed reaction of walruses to the vessels was a flight response, which is within their normal range of activity. Walruses vigorously flee predators such as killer whales and polar bears. However, unlike a passing ship, those encounters are likely to last for some time causing more stress as predators often spend time pursuing, testing, and manipulating potential prey before initiating an attack. As most observed animals exhibited minimal responses to Industry activity and relatively few animals exhibited a flight response, we do not anticipate that interactions will impact survival or reproduction of walruses at the individual or population level.

We do not know the length of time or distance traveled by walruses that approached, avoided, or fled from the vessels before resuming normal activities. However, it is likely that those responses lasted less than 30 minutes and covered less than 805 m (0.5 mi), based on data reported by the MMO programs.

MMO data collected in 2012 for 48 walrus observations indicate that walrus encounter times ranged from less than 1 to 31 minutes, averaging 3 minutes. The shortest duration encounters usually involved single animals that did not react to the vessel or dove and were not seen again. The longest duration encounter occurred when a vessel was moving through broken ice and encountered several groups of walruses in rapid succession. These data indicate that most encounters were of single animals where behavioral response times were limited to short durations.

During 2006–2011, observations from Industry activities in the Beaufort Sea indicate that, in most cases, walruses appeared undisturbed by human interactions. Walruses have hauled out on the armor of offshore drilling islands or coastal facilities and exhibited mild reactions (raise head and observe) to helicopter noise. There is no evidence that there were any physical effects or impacts to these individual walruses based on the observed interactions with Industry. A more detailed account of Industry-generated noise effects can be found in the *Potential Effects of Oil and Gas Industry Activities on Pacific Walruses and Polar Bears, Pacific Walrus, 1. Disturbance from Noise* section.

2. Cumulative Impacts

The 2010 status review of the Pacific walrus (Garlich-Miller *et al.* 2011) prepared by the Service (*http://alaska.fws.gov/fisheries/mmm/walrus/pdf/review_2011.pdf*) and Jay *et al.* (2012) describe natural and human factors that could contribute to cumulative effects that could impact walruses into the future. Factors other than oil and gas activities that could affect walruses within the 5-year period of these regulations include climate change, harvest, and increased shipping, all of which are discussed below.

A. Climate Change

Analysis of long-term environmental data sets indicates that substantial reductions in both the extent and thickness of the Arctic sea ice cover have occurred over the past 40 years. The record minimum sea ice extent occurred in September 2012 with 2002, 2005, 2007, 2009, 2010, and 2011 ice extent close to the record low and substantially below the 20-year mean (NSIDC 2012). Walruses rely on suitable sea ice as a substrate for resting between foraging bouts, calving, molting, isolation from predators, and protection from storm events. The juxtaposition of sea ice over shallow shelf habitat suitable for benthic feeding is important to walruses. The recent trend in the Chukchi Sea has resulted in seasonal sea ice retreat off the continental shelf and over deep Arctic Ocean waters, presenting significant adaptive challenges to walruses in the region. Observed impacts to walruses as a result of diminishing sea ice cover include: A northward shift in range and declines in Bering Sea haulout use; an increase in the speed of the spring migration; earlier formation and longer duration of Chukchi Sea coastal haulouts; and increased vulnerability to predation and disturbance while at Chukchi Sea coastal haulouts, resulting in increased mortality rates among younger animals. Postulated effects include: Premature separation of females and dependent calves; reductions in the prey base; declines in animal health and condition; increased interactions with development activities; population decline; and the potential for the harvest to become unsustainable.

Future studies investigating walrus distributions, population status and trend, harvest sustainability, and habitat use patterns in the Chukchi Sea are important for responding to walrus conservation and management issues associated with environmental and habitat changes.

Icebreaking by vessels is a concern to some who believe that this activity could accelerate climate change and detrimentally affect walrus or polar bear ice habitat. However, according to the National Snow and Ice Data Center (*http://nsidc.org/arcticseaicenews/faq/#icebreakers*), ''When icebreakers travel through sea ice, they leave trails of open water in their wake. Dark open water does not reflect nearly as much sunlight as ice does, so sometimes people wonder if icebreakers speed up or exacerbate sea ice decline. In summer, the passages created by icebreakers do increase *local* summertime melting because the ships cut through the ice and expose new areas of water to warm air. The melt caused by an icebreaker is small and localized. Channels created

by icebreakers are quite narrow and few in number compared to natural gaps in the ice. In winter, any openings caused by icebreakers will quickly freeze over again. Scientists do not think that icebreakers play a significant role in accelerating the decline in Arctic sea ice.'' More information on this topic is available at (*http://nsidc.org/icelights/2012/04/12/are-icebreakers-changing-the-climate/*).

For activities in the Chukchi Sea, Industry ice management will consist of actively pushing the ice off its trajectory with the bow of the ice management vessel, but some ice-breaking could be required for the safety of property and assets, such as a drill rig.

For our analysis, we determined that the only ice breaking that will occur would be if a large floe needed to be deflected from Industry equipment (including ships and drilling platforms), and it would be more efficient to break up that floe. For example, in 2012, ice management was required during a total of 7 days from 31 August to 13 September and was limited to 9 discrete isolated events, where ice was broken apart only two times. Further, if ice floes are too large, the drill rig will cease operations, secure the site, release the anchors, and move from the site until the floe has passed, as occurred in 2012 at the Burger A prospect, which required the drill ship to be off-site for 10 days.

B. Harvest

Walruses have an intrinsically low rate of reproduction and are thus limited in their capacity to respond to exploitation. In the late 19th century, American whalers intensively harvested walruses in the northern Bering and southern Chukchi seas. Between 1869 and 1879, catches averaged more than 10,000 per year, with many more animals struck and lost. The population was substantially depleted by the end of the century, and the commercial hunting Industry collapsed in the early 1900s. Since 1930, the combined walrus harvests of the United States and Russian Federation have ranged from 2,300 to 9,500 animals per year. Notable harvest peaks occurred during 1930 to 1960 (4,500 to 9,500 per year) and in the 1980s (7,000 to 16,000 per year). Commercial hunting continued in the Russian Federation until 1991, under a quota system of up to 3,000 animals per year. Since 1992, the harvest of walruses has been limited to the subsistence catch of coastal communities in Alaska and Chukotka. Harvest levels through the 1990s ranged from approximately 4,100 to 7,600 animals per year and 3,800 to 6,800 in the 2000s. As described in detail earlier in the Subsistence Use and Harvest Patterns of Pacific Walruses and Polar Bears section, recent harvest levels are lower than historic highs. The Service is currently working to assess population size and sustainable harvest rates.

C. Commercial Fishing and Marine Vessel Traffic

Available data suggest that walruses rarely interact with commercial fishing and marine vessel traffic. Walruses are normally closely associated with sea ice, which limits their interactions with fishing vessels and barge traffic. However, as previously noted, the temporal and seasonal extent of the sea ice is projected to diminish in the future. Commercial shipping through the Northwest Passage and Northern Sea Route may increase in coming decades. Commercial fishing opportunities may also expand should the sea ice continue to diminish. The result could be increased temporal and spatial overlap between fishing and shipping operations and walrus habitat use and increased interactions between walruses and marine vessels.

Hunting pressure, declining sea ice due to climate change, and the expansion of commercial activities into walrus habitat all have potential to impact walruses. Combined, these factors are expected to present significant challenges to future walrus conservation and management efforts. The success of future management efforts will rely in part on continued investments in research investigating population status and trend and habitat use patterns. Research by the U.S. Geological Survey (USGS) and the Chukotka Branch of the Pacific Fisheries Research Center examining walrus habitat use patterns in the Chukchi Sea is beginning to provide useable results (Jay *et al.* 2012). In addition, the Service is beginning to develop and test some methods for a genetic mark-recapture project to estimate walrus population size and trend and demographic parameters. The effectiveness of various mitigation measures and management actions will also need to be continually evaluated through monitoring programs and adjusted as necessary. The decline in sea ice is of particular concern, and will be considered in the evaluation of future activities and as more information on walrus population status becomes available.

Evaluation of Documented Impacts to Pacific Walrus

The projects, including the most extensive activities, such as seismic surveys and exploratory drilling operations, identified by the petitioners are likely to result in some incremental cumulative effects to walruses through the potential exclusion or avoidance of walruses from feeding or resting areas and the disruption of associated biological behaviors. However, based on the habitat use patterns of walruses in the Chukchi Sea and their close association with seasonal pack ice, relatively small numbers of walruses are likely to be encountered in the open sea conditions where most of the Industry activities are expected to occur. In the Hanna Shoal area, we can reliably predict that many walruses will likely remain even after the ice melts for foraging purposes. Because of this, Industry activities that occur near coastal haulouts within the HSWUA, or intersect travel corridors between haulouts and the HSWUA, may require close monitoring and additional special mitigation procedures, such as seasonal restrictions (e.g., July to September) of Industry activities from Hanna Shoal and rerouting vessel traffic and aircraft flights around walrus travel corridors. Required monitoring and mitigation measures, designed to minimize interactions between authorized projects and concentrations of resting or feeding walruses, are expected to limit interactions and trigger real time consultations if needed. Therefore, we conclude that the exploration activities, especially as mitigated through the regulatory process, are not at this time expected to add significantly to the cumulative impacts on the walrus population from past, present, and future activities that are reasonably likely to occur within the 5-year period covered by these regulations.

Polar Bear

Information regarding interactions between oil and gas activities and polar bears in the Chukchi and Beaufort seas has been collected for several decades. To date, most impacts to polar bears from Industry operations in the Chukchi Sea have been temporary disturbance events, some of which have led to deterrence actions. Monitoring efforts by Industry required under previous regulations for the incidental take of polar bears documented various types of interactions between polar bears and Industry (USFWS unpublished data). This analysis concentrates on the Chukchi Sea information collected through regulatory requirements and is useful in predicting how polar bears are likely to be affected by Industry activities.

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events, some of which have led to deterrence events. Monitoring efforts by Industry required under previous regulations for the incidental take of polar bears documented various types of interactions between polar bears and Industry.

1. Reported Observations

From 1989 to 1991, Shell Western E&P conducted drilling operations in the Chukchi Sea. A total of 110 polar bears were recorded from aerial surveys and from support and ice management vessels during the 3 years. In 1989, 18 bears were sighted in the pack ice during the monitoring programs associated with the drilling program. In 1990, a total of 25 polar bears were observed on the pack ice in the Chukchi Sea between June 29 and August 11, 1990. Seventeen bears were encountered by the support vessel, *Robert LeMeur,* during an ice reconnaissance survey before drilling began at the prospects. During drilling operations, four bears were observed near (<9 km or 5.5 mi) active prospects, and the remainder were considerably beyond the drilling operation (15 to 40 km or 9.3 to 24.8 mi). These bears responded to the drilling or icebreaking operations by approaching (two bears), watching (nine bears), slowly moving away (seven bears), or ignoring (five bears) the activities; response was not evaluated for two bears. During the 1991 drilling program, 64 polar bears were observed on the pack ice, and one was observed swimming south of the ice edge. The researchers of the 1990 monitoring program for the Shell exploration concluded that: (1) Polar bear distributions were closely linked to the pack ice; (2) the pack ice was near the active prospects for a brief time; and (3) the ice passing near active prospects contained few animals. These data were collected when sea ice in the region was more prevalent than today, and we anticipate that current and future operations will observe fewer bears; however, we expect that behaviorally the bears observed will react similarly.

Between 2006 and 2011, 16 offshore projects were issued incidental take authority for polar bears: Seven seismic surveys; four shallow hazards and site clearance surveys; and five environmental studies, including ice observation flights and onshore and offshore environmental baseline surveys. Observers associated with these 16 projects documented 62 individual bears in 47 different observations. These observations and bear responses are discussed below.

The majority of the bears were observed on land (50 percent; 31 of 62 polar bears). Twenty-one bears (34 percent) were recorded on the ice, mainly in unconsolidated ice on ice floes, and 10 bears (16 percent) were observed swimming in the water. Fifty-seven percent of the polar bears (35 of 62 bears) were observed from vessels, while 35 percent (22 of 62 bears) were sighted from aerial surveys and 8 percent (5 of 62 bears) were observed from the ground.

Of the 62 polar bears documented, 32 percent (20 of 62 bears) of the observations were recorded as Level B harassment takes, where the bears exhibited short-term, temporary reactions to the conveyance, vessel, plane, or vehicle, such as moving away from the conveyance. No polar bears were intentionally deterred. Sixty-five percent of the bears (40 of 62 bears) exhibited no behavioral reactions to the conveyance, while the reactions of 3 percent of the bears (2 of 62 bears) were unknown (not observed or not recorded). Most polar bears were observed during secondary or support activities, such as aerial surveys or transiting between project areas. These activities were associated with a primary project, such as a seismic operation. No polar bears were observed during active seismic operations.

Additionally, other activities have occurred in the Chukchi Sea region that have resulted in reports of polar bear sightings to the Service. Five polar bear observations (11 individuals) were recorded during the University of Texas at Austin's marine geophysical survey performed by the U.S. Coast Guard (USCG) Cutter *Healy* in 2006. All bears were observed on the ice between July 21 and August 19. The closest point of approach distances of bears from the *Healy* ranged from 780 m to 2.5 km (853 yards [yd] to 1.5 mi). One bear was observed approximately 575 m (628.8 yd) from a helicopter conducting ice reconnaissance. Four of the groups exhibited possible reactions to the helicopter or vessel, suggesting that disturbances from offshore vessel operations when they occur are short-term and limited to minor changes in behavior.

In 2007, a female bear and her cub were observed approximately 100 meters (110 yd) from a drill pad at the Intrepid exploration drilling site, located on the Chukchi Sea coast south of Barrow. The bear did not appear concerned about the activity and eventually the female changed her direction of movement and left the area.

Additional information exists on Industry and polar bear encounters from the Beaufort Sea (76 FR 47010; August 3, 2011). Documented impacts on polar bears by Industry in the Beaufort Sea during the past 30 years appear minimal. Polar bears spend time on land, coming ashore to feed, den, or move to other areas. Recent studies suggest that bears are spending more time on land than they have in the past in response to changing ice conditions.

Annual monitoring reports from Industry activities and community observations in the Beaufort Sea indicate that fall storms, combined with reduced sea ice, force bears to concentrate along the coastline (between August to October) where bears remain until the ice returns. For this reason, polar bears have been encountered at or near most coastal and offshore production facilities, or along the roads and causeways that link these facilities to the mainland. During those periods, the likelihood of interactions between polar bears and Industry activities increases. During 2011, in the Beaufort Sea region, companies observed 237 polar bears in 140 sightings on land and in the nearshore marine environment. Of the 237 bears observed in 2011, 44 bears (19 percent of the total observed) were recorded as Level B takes as they were deterred (hazed) away from facilities and people. Industry monitoring reports indicate that most bears are observed within a mile of the coastline. Similarly, we expect intermittent periods with high concentrations of bears to occur along the Chukchi Sea coastline as 50 percent of the bear encounters between 2006 and 2011 were documented in the onshore habitat.

While no lethal take of polar bears has occurred in the Chukchi Sea, a lethal take associated with Industry occurred at the Beaufort Sea Endicott facility in 2011, when a security guard mistakenly used a crackershell in place of a bean bag deterrent round and killed the bear during a deterrence action. Prior to issuance of regulations, lethal takes by Industry were rare. Since 1968, there have been two documented cases, one in the winter of 1968–1969, and one in 1990, of lethal take of polar bears associated with oil and gas activities; in both of these instances, the lethal take was reported to be in defense of human life.

2. Cumulative Impacts

Cumulative impacts of oil and gas activities are assessed, in part, through the information we gain in monitoring reports, which are a required component of each operator's LOA under the authorizations. We have over 20 years of monitoring reports, and the information on all incidental and intentional polar bear interactions

provides a comprehensive history of past effects of Industry activities on polar bears. We use the information on previous impacts to evaluate potential impacts from existing and future Industry activities and facilities. Additional information used in our cumulative effects assessment includes: Service, USGS, and other polar bear research and data; traditional knowledge of polar bear habitat use; anecdotal observations; and professional judgment.

While the number of LOAs being requested does not represent the potential for direct impact to polar bears, they do offer an index as to the effort and type of Industry activity that is currently being conducted. LOA trend data also help the Service track progress on various projects as they move through the stages of oil field development. An increase in Industry projects across the Arctic has the ability to increase bear-human interactions.

The Polar Bear Status Review describes cumulative effects of oil and gas development on polar bears in Alaska (see pages 175 to 181 of the status review). This document can be found at: *http://alaska.fws.gov/fisheries/mmm/polarbear/pdf/Polar_Bear_%20Status_Assessment.pdf.* The status review concentrated on oil and gas development in the Beaufort Sea because of the established presence of Industry in the Beaufort Sea. The Service believes the conclusions of the status review will apply to Industry activities in the Chukchi Sea during the 5-year timeframe of these regulations as the exploratory activities in the Beaufort Sea are similar to those in the Chukchi Sea.

In addition, in 2003, the National Research Council published a description of the cumulative effects that oil and gas development will have on polar bears and seals in Alaska. They concluded that:

(1) ''Industrial activity in the marine waters of the Beaufort Sea has been limited and sporadic and likely has not caused serious cumulative effects to ringed seals or polar bears.'' Industry activity in the Chukchi Sea during the timeframe of these regulations will be limited to exploration activities, such as seismic, drilling, and support activities.

(2) ''Careful mitigation can help to reduce the effects of oil and gas development and their accumulation, especially if there is no major oil spill.'' The Service will use mitigation measures similar to those established in the Beaufort Sea to limit impacts of polar bears in the Chukchi Sea. ''However, the effects of full scale industrial development off the North Slope will accumulate through the displacement of polar bears and ringed seals from their habitats, increased mortality, and decreased reproductive success.'' Full-scale development of this nature will not occur during the prescribed timeframe of these regulations in the Chukchi Sea.

(3) ''A major Beaufort Sea oil spill would have major effects on polar bears and ringed seals.'' One of the concerns for future oil and gas development is for those activities that occur in the marine environment due to the chance for oil spills to impact polar bears or their habitats. No production activities are planned for the Chukchi Sea during the duration of these regulations. Oil spills as a result of exploratory drilling activity could occur in the Chukchi Sea; however, the probability of a large spill at the exploration stage is expected to be low.

(4) ''Climatic warming at predicted rates in the Beaufort and Chukchi seas region is likely to have serious consequences for ringed seals and polar bears, and those effects will accumulate with the effects of oil and gas activities in the region.'' The Service is currently working to minimize the impacts of climate change on its trust species. The implementation of ITRs is one effective way to address and minimize impacts to polar bears.

(5) ''Unless studies to address the potential accumulation of effects on North Slope polar bears or ringed seals are designed, funded, and conducted over long periods of time, it will be impossible to verify whether such effects occur, to measure them, or to explain their causes.'' Current studies in the Chukchi Sea are examining polar bear habitat use and distribution, reproduction, and survival relative to a changing sea ice environment.

Climate change, predominantly through sea ice decline, will alter polar bear habitat because seasonal changes, such as extended duration of open water, will preclude sea ice habitat use by restricting some bears to coastal areas. Biological effects on polar bears are expected to include increased movements or travel, changes in bear distribution throughout their range, changes to the access and allocation of denning areas, and increased open water swimming. Demographic effects that may be influenced by climate change include changes in prey availability to polar bears, a potential reduction in the access to prey, and changes in seal productivity.

In the Chukchi Sea, it is expected that the reduction of sea ice extent will affect the timing of polar bear seasonal movements between the coastal regions and the pack ice. If the sea ice continues to recede as predicted, the Service anticipates that there may be an increased use of terrestrial habitat in the fall period by polar bears on the western coast of Alaska and an increased use of terrestrial habitat by denning bears in the same area, which may expose bears to Industry activity. Mitigation measures will be effective in minimizing any additional effects attributed to seasonal shifts in distributions of denning polar bears during the 5-year timeframe of these regulations. It is likely that, due to potential seasonal changes in abundance and distribution of polar bears during the fall, more frequent encounters may occur and that Industry may have to implement mitigation measures more often, for example, increasing polar bear deterrence events. As with the Beaufort Sea, the challenge in the Chukchi Sea will be predicting changes in ice habitat and coastal habitats in relation to changes in polar bear distribution and use of habitat.

A detailed description of climate change and its potential effects on polar bears by the Service can be found in the documents supporting the decision to list the polar bear as a threatened species under the ESA at: *http://alaska.fws.gov/fisheries/mmm/polarbear/esa.htm#listing.* Additional detailed information by the USGS regarding the status of the SBS stock in relation to decreasing sea ice due to increasing temperatures in the Arctic, projections of habitat and populations, and forecasts of range-wide status can be found at: *http://www.usgs.gov/newsroom/special/polar_bears.*

The activities (drilling operations, seismic surveys, and support operations) identified by the petitioners are likely to result in some incremental cumulative effects to polar bears during the 5-year timeframe of these regulations. This could occur through the potential exclusion or avoidance of polar bears from feeding, resting, or denning areas and disruption of associated biological behaviors. However, the level of cumulative effects, including those of climate change, during the 5-year timeframe of these regulations are projected to result in negligible effects on the bear population.

Evaluation of Documented Impacts on Polar Bears

Monitoring results from Industry, analyzed by the Service, indicate that little to no short-term impacts on polar bears have resulted from oil and gas activities. We evaluated both subtle and acute impacts likely to occur from industrial activity, and we determined

that all direct and indirect effects, including cumulative effects, of industrial activities have not adversely affected the species through effects on rates of recruitment or survival. Based on past monitoring reports, the level of interaction between Industry and polar bears has been minimal and provides evidence that these populations have not been adversely affected. For the 5-year timeframe of these regulations, we anticipate the level of oil and gas Industry interactions with polar bears would likely increase in response to more bears on shore and more activity along the coast; however we do not anticipate significant impacts on bears to occur.

Summary of Take Estimates for Pacific Walruses and Polar Bears

Small Numbers Determination

As discussed in the ''Biological Information'' section, the dynamic nature of sea ice habitats influences seasonal and annual distribution and abundance of polar bears and walruses in the specified geographical region (eastern Chukchi Sea). The following analysis demonstrates that, with these regulations, only small numbers of walruses and polar bears are likely to be taken incidental to the described Industry activities. This analysis is based upon known distribution patterns and habitat use of walruses and polar bears.

Pacific Walrus

The Service has based its small numbers determination on an examination of the best available information concerning the range of this species and its habitat use patterns (see Biological Information for additional details); information regarding the siting, timing, scope, and footprint of Industry activities (see Description of Activities for additional details); information regarding monitoring requirements and mitigation measures designed to avoid and mitigate incidental take of walruses during authorized activities (see Section 18.118 Mitigation, Monitoring, and Reporting Requirements in the Final Regulation Promulgation section for additional details); and the Chukchi Sea Lease Sale 193 stipulations by the Mineral Management Service (now BOEM in February 2008 regarding protection of biological resources. The objective of this analysis is to determine whether or not Industry activities described in the ITR petition are likely to impact small numbers of individual animals.

The specified geographic region covered by this request includes the waters (State of Alaska and OCS) and bed of the Chukchi Sea, as well as terrestrial habitat up to 40 km (25 mi) inland (Figure 1; see Final Regulation Promulgation section). The marine environment and terrestrial coastal haulouts are considered walrus habitat for this analysis. The petition specifies that offshore exploration activities will be limited to the July 1 to November 30 open-water season to avoid seasonal pack ice. Furthermore, the petition specifies that onshore or near shore activities will not occur in the vicinity of coastal walrus haulouts. Oil and gas activities anticipated and considered in our analysis include: (1) Offshore exploration drilling; (2) offshore 3D and 2D seismic surveys; (3) shallow hazards surveys; (4) other geophysical surveys, such as ice gouge, strudel scour, and bathymetry surveys; (5) geotechnical surveys; (6) onshore and offshore environmental studies; and (7) associated support activities for the aforementioned activities. A full description of these activities can be found in this document in the Description of Activities section.

Distribution of Walruses During the Open-Water Season

During the July to November open-water season, the Pacific walrus population ranges well beyond the boundaries of the specified geographic region (Figure 1; see Final Regulation Promulgation section). Based on population surveys, haulout monitoring studies, and satellite tracking studies, the population generally occurs in three areas: The majority of males remain in the Bering Sea outside of the specified geographic region. Juveniles, adult females, and calves are distributed in the western Chukchi Sea in the vicinity of both Wrangel and Herald Islands in Russian waters. Another subset of females and young are in the eastern Chukchi Sea, which includes the specified geographic region, with high densities in the Hanna Shoal area (Fay 1982; Jay *et al.* 2012). Therefore, the animals in the northeast Chukchi Sea that could potentially be influenced by Industry activities represent only a portion of the overall population.

Though the specified geographic region of these regulations (Figure 1; see Final Regulation Promulgation section) includes areas of potential walrus habitat, the actual area of Industry activities occurring within this region will be relatively small. The entire Chukchi Sea is approximately 600,000 km^2 (231,660 mi^2). The area of the specified geographic region (Figure 1; see Final Regulation Promulgation section) is approximately 240,000 km^2 (92,664 mi^2), and the area covered by Lease Sale 193 offered in 2006 was approximately 138,000 km^2 (53,282 mi^2), with currently active leases covering approximately 11,163 km^2 (4,310 mi^2). The Chukchi Sea is only a portion of the overall Pacific walrus range, and though most of it contains suitable walrus habitat, some portions are not suitable (e.g., where water depths exceed 100 m). However, if we assume that the entire 600,000 km^2 (231,660 mi^2) of the Chukchi Sea is utilized by walruses, then the specified geographic region (Figure 1; see Final Regulation Promulgation section) covers approximately 40 percent, Lease Sale 193 area covers approximately 23 percent, and current active leases cover approximately 2 percent of the Chukchi Sea, respectively. In any single year, and over the 5-year period of these regulations, Industry activity will only occur on a portion of the active lease area. For example, AOGA indicates in its petition that one seismic survey will occur each year during the 5-year period of these regulations. AOGA further estimates that a typical marine 3D seismic survey is expected to ensonify approximately 1680 km^2 (649 mi^2) of sea floor. This equates to roughly 15 percent of the active lease area, 0.7 percent of the specified geographic region (Figure 1; see Final Regulation Promulgation section), and 0.28 percent of the Chukchi Sea per year, respectively.

We anticipate that Industry activities will impact a relatively small proportion of the potential walrus habitat in the specified geographical region at any given time, whether or not the habitat is occupied by walruses. The narrow scope and footprint of activities that will occur in any given year limits the potential for Industry to interact with the subset of the walruses that may be distributed in the eastern Chukchi Sea during the open-water season.

Habitat Use Patterns in the Specified Geographic Region

The subset of the overall walrus population residing in the eastern Chukchi Sea can be widespread and abundant depending on ice conditions and distribution. Walruses typically migrate into the region in early June along lead systems that form along the coast. Walruses summering in the eastern Chukchi Sea exhibit strong selection for sea ice habitats. Previous aerial survey efforts in the area found that 80 to 96 percent of walruses were closely associated with sea ice habitats, and that the number of walruses observed in open water habitats

decreased significantly with distance from the pack ice (Gilbert 1999).

The distribution of the subset of the walrus population that occurs in the specified geographic region (Figure 1; see Final Regulation Promulgation section) each year is primarily influenced by the distribution and extent of seasonal pack ice, which is expected to vary substantially both seasonally and annually. In June and July, scattered groups of walruses are typically associated with loose pack ice habitats between Icy Cape and Point Barrow (Fay 1982; Gilbert *et al.* 1992). Recent walrus telemetry studies investigating foraging patterns suggest that many walruses focus foraging efforts near Hanna Shoal in the eastern Chukchi Sea, northwest of Point Barrow (Jay *et al.* 2012). In August and September, concentrations of animals tend to be in areas of unconsolidated pack ice, usually within 100 km (62 mi) of the leading edge of the ice pack (Gilbert 1999). Individual groups occupying unconsolidated pack ice typically range from fewer than 10 to more than 1,000 animals (Gilbert 1999; Ray *et al.* 2006). In August and September, the edge of the pack ice generally retreats north to approximately 71° N latitude (the majority of active lease blocks are between 71 and 72° N), but in light ice years can retreat north of the continental shelf (Douglas 2010), about 73 to 75° N. Sea ice normally reaches its minimum (northern) extent in September, and ice begins to reform rapidly in October and November. Walruses typically migrate out of the eastern Chukchi Sea in October in advance of the developing sea ice (Fay 1982; Jay *et al.* 2012).

Sea ice has historically persisted in the Chukchi Sea region through the entire year although the extent of sea ice cover over continental shelf areas during the summer and fall has been highly variable. Over the past decade, sea ice has begun to retreat beyond shallow continental shelf waters in late summer. For example, in 5 of the last 8 years (2004 to 2012), the continental shelf waters of the eastern Chukchi Sea have become ice free in late summer, for a period ranging from a few weeks up to 2 months. Climate-based models suggest that the observed trend of rapid ice loss from continental shelf regions of the Chukchi Sea is expected to persist, and perhaps accelerate in the future (Douglas 2010).

Based on telemetry studies, during periods of minimal or no-ice cover over continental shelf regions of the eastern Chukchi Sea, we expect that most walruses in that subset of the population will either migrate out of the region beyond the scope of Industry activities in pursuit of more favorable ice habitats (i.e., the western Chukchi Sea), or relocate to coastal haulouts where they can rest on land between foraging excursions (Jay *et al.* 2012*).* Walruses occupying coastal haulouts along the Chukchi Sea coast tend to aggregate in large dense groups, which are vulnerable to disturbances that can result in trampling injuries and mortalities (Garlich-Miller *et. al.* 2011). The AOGA petition specifically notes that Industry activities will not occur near coastal walrus haulouts. In addition, OCS Lease Sale Area 193 excluded a 40-km (25-mi) coastal buffer zone from the lease area to protect sensitive coastal habitats and mitigate potential interactions with subsistence hunting activities along the coast. We expect that a similar coastal buffer zone will be included in future lease sales in the region. Moreover, required mitigation measures for authorized activities pursuant to the final ITRs expressly forbid operating near coastal walrus haulouts (see mitigation measures below). For example, all support vessels and aircraft will be required to maintain a 1-mile buffer area around groups of walruses hauled out on land. Because of these limitations on authorized activities near coastal walrus haulouts, we do not expect that any takes will occur at coastal haulouts from Industry activities.

We expect that the density of walruses in offshore, open water environments, where most exploration activities are expected to occur, will be relatively low. Based on previous aerial survey efforts in the region (Gilbert 1999) and satellite tracking of walrus distributions and movement patterns in the region (Jay *et al.* 2012), we expect that most walruses in the subset of the overall population in the specified geographic region will be closely associated with broken pack ice during the open-water season. This would limit the exposure of walruses to seismic surveys and exploratory drilling operations, where we expect Industry operations to avoid these areas of broken ice cover in order to avoid damaging their equipment. Furthermore, during the open-water season, walruses could also occupy coastal haulouts when ice concentrations are low in offshore regions.

Telemetry studies investigating the foraging behavior of walruses at coastal haulouts indicate that most animals forage within 30 to 60 km (19 to 37 mi) of coastal haulouts (Fischbach *et al.* 2010), primarily within the 40-km (25-mi) coastal buffer, which is closed to seismic surveys and drilling. However, some animals appear to make long foraging excursions from coastal haulouts to offshore feeding areas near Hanna Shoal (about 180 km, 112 mi from Point Lay, AK) (Jay *et al.* 2012). This movement pattern is also apparent based on walrus vocalizations recorded at buoys placed throughout the area in 2010 (Delarue *et al.* 2012). Given this observed behavior, we expect that the density of walruses in the HSWUA could be relatively high compared with other offshore regions, even during periods of minimal sea ice cover. Most of the lease sale blocks in the HSWUA region are currently not leased. Based on the significant biological value of HSWUA to walrus foraging, and the likelihood of encountering large groups of foraging walruses in that area through September, additional mitigation measures may be anticipated to limit disturbances and impacts to Pacific walruses when they are using this area.

Authorized Industry activities occurring near Hanna Shoal could potentially encounter groups of walruses moving from other areas, including coastal haulouts. The timing and movement routes between coastal haulouts and offshore foraging areas are not known, and are likely to vary from year to year. Although it is difficult to predict where groups of moving or feeding walruses are likely to be encountered in offshore open water environments, monitoring requirements and adaptive mitigation measures are expected to limit interactions with groups of walruses encountered in open water habitats. For example, all authorized support vessels must employ MMOs to monitor for the presence of walruses and other marine mammals. Vessel operators are required to take every precaution to avoid interactions with concentrations of feeding or moving walruses, and must maintain a minimum 805-m (0.5-mi) operational exclusion zone around walrus groups encountered in open water. Although monitoring requirements and adaptive mitigation measures are not expected to completely eliminate interactions with walruses in open water habitats, they are expected to limit takes to relatively small numbers of animals.

In summary, based upon scientific knowledge of the habitat use patterns of walruses in the specified region, we expect the number of animals using pelagic waters during the operating season to be small relative to the number of animals using habitats preferred by and more favorable to walruses (i.e., pack ice habitats and/or coastal haulouts and near-shore environments). Industry will not be

operating in areas with extensive ice cover due to their own operating limitations, and therefore Industry activities will avoid preferred walrus habitats. Further regulatory restrictions, such as stipulations on activities near haulouts, will ensure that Industry activities will not occur in or near those preferred walrus habitat areas. Moreover, it is possible that LOAs may not be issued for seismic and drilling activities in the HSWUA. Industry requests for incidental take authorization in the HSWUA during seasons of high walrus use will be considered on a case-by-case basis and Industry may be required to implement increased mitigation measures.

Most of the Industry oil and gas exploration activity is projected to occur in offshore areas under open water conditions where densities of walruses are expected to be low. Support vessels and aircraft transiting through areas of broken ice habitat where densities of walruses may be higher will be required to employ monitoring and adaptive mitigation measures intended to reduce interactions with walruses. Accordingly, in consideration of the habitat characteristics where most exploration activities are expected to occur (open-water environments) and specific mitigation measures designed to reduce potential interactions with walruses and other marine mammals, we expect that interactions will be limited to relatively small numbers of animals compared to the number of walruses in the specified geographic region as well as the overall population.

The Use of Monitoring Requirements and Mitigation Measures

We believe the mitigation measures and monitoring requirements we have included in this rule are effective in ensuring the ''least practicable adverse impact'' from oil and gas exploration activities to Pacific walruses in the Chukchi Sea. Similar mitigation measures and monitoring requirements in prior incidental take authorizations for the Chukchi Sea have proved highly effective at eliminating or mitigating adverse impacts to Pacific walruses. In addition, the mitigation measures in this rule have been updated with the best available scientific evidence, and in some instances, these measures have been made more restrictive on Industry activities.

Holders of an LOA must use methods and conduct activities in a manner that minimizes adverse impacts on walruses to the greatest extent practicable. Monitoring programs are required to inform operators of the presence of marine mammals and sea ice. Adaptive management responses based on real-time monitoring information (described in these final regulations) will be used to avoid or minimize interactions with walruses. Adaptive management approaches, such as temporal or spatial limitations in response to the presence of walruses in a particular place or time, or in response to the occurrence of walruses engaged in a particularly sensitive activity, such as feeding, will be used to avoid or minimize interactions with walruses.

However, monitoring programs can always be improved. Determining the longer-term impacts of Industry activities on marine mammals is important in assessing the negligible impact requirement of the MMPA. Monitoring programs currently detect animals at the surface in proximity to vessels to initiate mitigation measures. Monitors also document some of the immediate reactions of animals in immediate proximity to Industry activities. However, as there are no ''controls'' or reference data, the ability of the Service to estimate the full impacts of these activities is limited. In addition, we know little about the longer-term response of animals to various types of anthropogenic stimulus. Both of these types of data will help better inform the determination of a negligible impact as required under the MMPA. To estimate longer term impacts, there is a need to be able to monitor animals after exposure to any given activity for an extended period. One way to acquire this data is a random sampling of individuals and observations of those individuals prior to, during, and following an encounter. This type of study may require the use of additional vessels or aircraft or telemetry equipment to track animals encountered for extended periods of time. For example, resting walruses flushed from an ice floe would need to be tracked until they subsequently hauled out on the ice to rest. The Service sees the potential development of this type of study as an effort that could be jointly and cooperatively undertaken by this process between Industry and the regulatory agencies. When opportunities arise for these types of cooperative activities, we believe Industry and the regulatory agencies should work together to capitalize on them to further our understanding of impacts to animals and address remaining information. The inclusion in the monitoring and mitigation measures of the ''track animals'' stipulation is to provide a mechanism by which the Service may work with Industry to accomplish this goal. If such studies were pursued, appropriate scientific research permits would need to be obtained.

A full description of the mitigation, monitoring, and reporting requirements associated with LOAs under these regulations can be found in Section 18.118 Mitigation, Monitoring, and Reporting Requirements in the Final Regulation Promulgation section. Some of the mitigation measures expected to limit interactions with walruses will include:

1. Industry operations are not permitted in the geographic region until July 1. This condition is intended to allow walruses the opportunity to disperse from the confines of the spring lead system and minimize Industry interactions with subsistence walrus hunters.

2. Vessels must be staffed with MMOs to alert crew of the presence of walruses and initiate adaptive mitigation responses when walruses are encountered.

3. Vessels should take all practical measures (i.e., reduce speed, change course heading) to maintain a minimum 805-m (0.5-mi) operational exclusion zone around groups of 12 or more walruses encountered in the water. Vessels may not be operated in such a way as to separate members of a group of walruses. We note that we reviewed the data on Industry encounters with walruses during 1989, 1990, and 2006–2012 and calculated the average size of groups of walruses which was 16 in 1989, 13 in 1990, and 7 from 2006–2012 resulting in a mean of 12. Observations of 12 or more walruses at the surface of the water likely represent a larger number of walruses in the immediate area that are not observed (possibly 70 or more).

4. Set back distances have been established between walruses and vessels to minimize impacts and limit disturbance. These set back distances are 805 m (0.5 mi) when walruses are observed on ice and in the water, and 1,610 m (1 mi) when observed on land.

5. Set back distances have been established between walruses and aircraft to minimize impacts and limit disturbance. No fixed-wing aircraft may operate at an altitude lower than 457 m (1,500 ft) within 805 m of walrus groups observed on ice, or within 1,610 m (1 mi) of walrus groups observed on land. No rotary winged aircraft (helicopter) may operate at an altitude lower than 914 m (3,000 ft) elevation within a lateral distance of 1,610 m (1 mi) of walrus groups observed on land. These operating conditions are intended to avoid and mitigate the potential for walruses to be flushed from ice floes or

land-based haulouts. In past regulations, the altitude associated with rotary-winged aircraft was 1,500 ft. However, we have determined that walruses at land-based haulouts are more susceptible to disturbance and have increased the height restriction, which in turn should decrease the possibility of disturbance.

6. Operators must maintain a minimum spacing of 24 km (15 mi) between all active seismic-source vessels and/or drill rigs during exploration activities to avoid significant synergistic or cumulative effects from multiple oil and gas exploration activities on foraging or migrating walruses. This does not include support vessels for these operations.

7. Any offshore exploration activity expected to include the production of downward-directed, pulsed underwater sounds with sound source levels ≥160 dB re 1 μPa will be required to establish and monitor acoustic exclusion and disturbance zones.

8. Trained MMOs must establish acoustically verified exclusion zones for walruses surrounding seismic airgun arrays where the received level would be ≥ 180 dB re 1 μPa and ≥ 160 dB re 1 μPa in order to monitor incidental take.

9. Whenever 12 or more walruses are detected within the acoustically verified 160-dB re 1 μPa disturbance zone ahead of or perpendicular to the seismic vessel track, operators must immediately power down or shut down the seismic airgun array and/or other acoustic sources to ensure sound pressure levels at the shortest distance to the aggregation do not exceed 160-dB re 1 μPa, and operators cannot begin powering up the seismic airgun array until it can be established that there are no walrus aggregations within the 160-dB disturbance zone based upon ship course, direction to walruses, and distance from last sighting.

These monitoring requirements and mitigation measures are not expected to completely eliminate the potential for walruses to be taken incidental to Industry activities in the region; however, they are expected to significantly reduce the number of takes and the number of walruses affected. By substantially limiting the season of operation and by requiring buffer areas around groups of walruses on land, ice, and in open water areas, we conclude that mitigation measures will significantly reduce the number of walruses incidentally taken by Industry activities.

Pacific Walrus Small Number Conclusion

Based upon our review of the best scientific information available, we conclude that Industry activities described in the AOGA petition will impact a relatively small number of walruses both within the specified geographical region and at the broader population scale. The information available includes the range, distribution, and habitat use patterns of Pacific walruses during the operating season, the relatively small footprint and scope of authorized projects both within the specified geographic region and on a broader scale within the known range of this species during the open-water season, and consideration of monitoring requirements and adaptive mitigation measures intended to avoid and limit the number of takes to walruses encountered through the course of authorized activities.

Polar Bears

Distribution of Polar Bears During the Open-Water Season

The number of polar bears occupying the specified geographical region during the open-water exploration season, when the majority of Industry activities are anticipated to occur, is expected to be smaller than the number of animals distributed throughout their range. Polar bears range well beyond the boundaries of the geographic region of the ITRs and the Chukchi Sea Lease Sale area. Even though they are naturally widely distributed throughout their range, a relatively large proportion of bears from the CS population utilize the western Chukchi Sea region of the Russian Federation during the open-water season. Concurrently, polar bears from the SBS population predominantly utilize the central Beaufort Sea region of the Alaskan and Canadian Arctic during this period. These areas are well outside of the geographic region of these regulations. Movement data and habitat use analysis of bears from the CS and SBS populations suggest that they utilize the ice habitat as a platform to survive, by feeding and resting. As the ice recedes, the majority of the bears ''move'' with it. A small portion of bears can be associated with the coast during the open-water season. In addition, open water is not selected habitat for polar bears and bears observed in the water likely try to move to a more stable habitat platform, such as sea ice or land.

As stated earlier, though the specified geographic region described for these regulations (Figure 1; see Final Regulation Promulgation section) includes areas of polar bear habitat, the actual area of Industry activity occurring within this region will be relatively small. The entire Chukchi Sea is approximately 600,000 km² (231,660 mi²). The area of the specified geographic region (Figure 1; see Final Regulation Promulgation section) is approximately 240,000 km² (92,664 mi²), the lease sale 193 area offered for leases was approximately 138,000 km² (53,282 mi²) with active leases of approximately 11,163 km² (4,310 mi²). The Chukchi Sea is only a portion of the overall polar bear range and though most of it contains suitable polar bear habitat, some portions are not suitable. However, if we conservatively assume that the entire approximately 600,000 km² (231,660 mi²) of the Chukchi Sea is utilized by polar bears, then the specified geographic region (Figure 1; see Final Regulation Promulgation section) covers approximately 40 percent, the lease sale 193 area approximately 23 percent, and current active leases are approximately 2 percent of that area, respectively. In any single year, and over the 5-year period of these regulations, Industry activity will occur only on a portion of the active lease area. The area of individual marine activities is expected to comprise a small percentage of the lease area. Vessel operations will be operating in habitats where polar bear densities are expected to be lowest, that is, open water. Although it is impossible to predict with certainty the number of polar bears that might be present in the offshore environment of the lease sale area in a given year, or in a specific project area during the open-water season, based on habitat characteristics where most exploration activities will occur (open-water environments) and based on scientific knowledge and observation of the species, only small numbers of polar bears are expected to contact Industry operations, and of those, only a small percentage will exhibit behavioral responses constituting take.

Likewise, the number of polar bears expected to be incidentally taken by Industry activities is a small proportion of the species' abundance. The estimate for Level B incidental take of polar bears is based on the past monitoring data from 2006 to 2011; the timing (open-water season) of the primary, off-shore Industry activities in the Chukchi Sea region; and the limited use of the pelagic environment by polar bears during the open-water season. The estimated total Level B incidental take for polar bears is expected to be 25 animals per year. This is a conservative estimate which takes into account that

between 2006 to 2011, only 20 polar bears of the 62 polar bears documented by Industry exhibited behavioral responses equivalent to Level B harassment takes (3.3 Level B takes of bears/year). This number is less than 1 percent of the estimated combined populations of the CS and SBS polar bear stocks (approximately 2,000 and 1,500, respectively). This estimate reflects the low densities of polar bears occurring in the Alaska region of the Chukchi Sea during the open-water period. The majority of interactions between polar bears and Industry are expected to occur near the pack ice edge habitat and in the terrestrial environment, where this estimate anticipates a potential increase of bears interacting with terrestrial facilities through the duration of the regulatory period (2013 to 2018).

Habitat Use Patterns in the Specified Geographic Region

Within the specified geographic region, the number of polar bears utilizing open water habitats, where the primary activity (offshore exploration operations) would occur, is expected to be small relative to the number of animals utilizing pack ice habitats or coastal areas. Polar bears are capable of swimming long distances across open water (Pagano *et al.* 2012). However, polar bears remain closely associated with primarily sea ice (where food availability is high) during the open-water season (Durner *et al.* 2004). A limited number of bears could also be found in coastal areas. We expect the number of polar bears using pelagic waters during open-water exploration activities to be very small relative to the number of animals exploiting more favorable habitats in the region (i.e., pack ice habitats and/or coastal haulouts and near shore environments).

In addition, a small portion of terrestrial habitat used by polar bears may be exposed to Industry activities. As detailed in the section ''Description of Geographic Region,'' terrestrial habitat encompasses approximately 10,000 km^2 (3,861 mi^2) of the NPR–A. Bears can use the terrestrial habitat to travel and possibly den and a smaller portion of this habitat situated along the coast could be potential polar bear denning habitat. However, the majority of coastal denning for the Chukchi Sea bears occurs along the Chukotka coast in the Russian Federation, outside of the geographic region. Hence, Industry activities operating on the Alaskan coast have the potential to impact only a small number of bears. Additionally, where terrestrial activities may occur in coastal areas of Alaska in polar bear denning habitat, specific mitigation measures will be required to minimize Industry impacts.

The Use of Monitoring Requirements and Mitigation Measures

Holders of an LOA must adopt monitoring requirements and mitigation measures designed to reduce potential impacts of their operations on polar bears. Restrictions on the season of operation (July to November) for marine activities are intended to limit operations to ice-free conditions when polar bear densities are expected to be low in the area of Industry operation. Additional mitigation measures could also occur near important polar bear habitat. Specific aircraft or vessel traffic patterns will be implemented when appropriate to minimize potential impacts to animals. Monitoring programs are required to inform operators of the presence of marine mammals and sea ice incursions. Adaptive management responses based on real-time monitoring information (described in these final regulations) will be used to avoid or minimize interactions with polar bears. For example, for Industry activities in terrestrial environments where denning polar bears may be a factor, mitigation measures will require that den detection surveys be conducted and Industry will maintain at least a 1-mile distance from any known polar bear den. A full description of the required Industry mitigation, monitoring, and reporting requirements associated with an LOA can be found in 50 CFR 18.118. While these regulations describe a suite of general requirements, additional mitigation measures could be developed at the project level given site-specific parameters or techniques developed in the future that could be more appropriate to minimize Industry impacts.

Polar Bear Small Number Conclusion

We anticipate a low number of polar bears at any given time in the areas the Service anticipates Industry operations to occur, and given the size of the operations and the mitigation factors anticipated, the likelihood of impacting individual animals is low. We anticipate that the type of take will be similar to that observed in 2006 to 2011, i.e., nonlethal, minor, short-term behavioral changes that will not cause a disruption in normal activities of polar bears. In addition, these takes are unlikely to have cumulative effects from year to year as the response of bears will be short-lived, behavioral or physiological responses, and the same individuals are unlikely to be exposed in subsequent years. Overall, these takes (25 annually) are not expected to result in adverse effects that will influence population-level reproduction, recruitment, or survival.

Small Number Summary and Conclusion

To summarize, relative to species abundance, only a small number of the Pacific walrus population and the Chukchi/Bering Sea and Southern Beaufort Sea polar bear populations will be impacted by Industry activities. This statement can be made with a high level of confidence because:

(1) Pacific walruses and polar bears are expected to remain closely associated with either sea ice or coastal zones, predominantly the Russian Federation coast, where food availability is high and not in open water where Industry activities will occur.

(2) Vessel observations from 2006 to 2011 recorded encountering 11,125 walruses, which is a small percentage of the overall walrus population. Of this small percentage of walruses observed, only 2,448 individuals appeared to have exhibited mild forms of behavioral response, such as being attentive to the vessel. During the same 6-year period, 62 polar bears were observed, which is a small percentage of the overall Alaskan population. Of this small percentage of observed polar bears, only 20 individuals exhibited mild forms of behavioral response.

(3) The restrictive monitoring and mitigation measures that will be required of Industry activity will further reduce the number of animals encountered and minimize any potential impacts to those individuals encountered.

(4) The continued predicted decline in sea ice extent as the result of climate change is anticipated to further reduce the number of polar bears and walruses occurring in the specified geographic area during Industry activities because neither species prefers using the open water environment. This will further reduce the potential for interactions with Industry activities during the open-water season.

In conclusion, given the spatial distribution, habitat requirements, and applicable data, the number of animals interacting with Industry activities will be small compared to the total Pacific walrus and the Chukchi and Southern Beaufort Sea polar bear populations. Moreover, not all interactions will result in a taking as defined under the MMPA, which will reduce the numbers even further.

Negligible Effects Determination

Based upon our review of the nature, scope, and timing of the proposed Industry activities and mitigation measures, and in consideration of the best available scientific information, it is our determination that the activities will have a negligible impact on walruses and on polar bears. We considered multiple factors in our negligible effects determination.

The predicted impacts of Industry activities on walruses and polar bears will be nonlethal, temporary, passive takes of animals. The documented impacts of previous similar Industry activities on walruses and polar bears, taking into consideration cumulative effects, provides direct information that the Industry activities analyzed for this final rule are likely to have minimal effects on individual polar bears and Pacific walruses. All anticipated effects will be short-term, temporary behavioral changes, such as avoiding the activity and/or moving away from the activity. Any minor displacement will not result in more than negligible impacts because habitats of similar value are not limited to the area of immediate activity and are abundantly available within the region. The Service does not anticipate that these impacts will cause disruptions in normal behavioral patterns of affected animals. The Service predicts the impacts of Industry activities on walruses and polar bears will be infrequent, sporadic, and of short duration. Additionally, impacts will involve passive forms of take and are not likely to adversely affect overall population reproduction, recruitment, or survival. The potential effects of Industry activities are discussed in detail in the section ''Potential Effects of Oil and Gas Industry Activities on Pacific Walruses and Polar Bears.''

A review of similar Industry activities and associated impacts in 2006 to 2011 in the Chukchi Sea, where the majority of the proposed activities will occur, help us predict the type of impacts and their effects that will likely occur during the timeframe of these regulations. Vessel-based monitors reported 11,125 walrus sightings during Industry seismic activity from 2006 to 2011. Approximately 7,310 animals exhibited no response to the vessels while 2,448 of the walruses sighted exhibited some form of behavioral response to stimuli (auditory or visual) originating from the vessels, primarily exhibiting attentiveness, approach, avoidance, or fleeing. Again, other than a short-term change in behavior, no negative impacts were noted, and the numbers of animals demonstrating a change in behavior was small in comparison to those observed in the area.

During the same time, polar bears documented during Industry activities in the Chukchi Sea were observed on land, on ice, and in the water. Bears reacted to the human presence, whether the conveyance was marine, aerial, or ground-based, by distancing themselves from the conveyance. In addition, polar bear reactions recorded during activities suggested that 65 percent of the bears (45 of 62 individual bears) observed elicited no reaction at all to the human presence. Thirty-two percent of the bears exhibited temporary, minor changes in behavior.

Mitigation measures will limit potential effects of Industry activities. As described above in the Small Numbers Determination, holders of an LOA must adopt monitoring requirements and mitigation measures designed to reduce potential impacts of their operations on walruses and polar bears. Seasonal restrictions, required monitoring programs to inform operators of the presence of marine mammals and sea ice incursions, den detection surveys for polar bears, and adaptive management responses based on real-time monitoring information (described in these final regulations) will all be used to avoid or minimize interactions with walruses and polar bears and therefore limit Industry impacts on these animals. First, restricting Industry activities to the open-water season (July to November) will ensure that walruses reach preferred summering areas without interference and polar bears are able to exploit sea ice habitats in active lease sale areas. Second, MMOs on all vessels will inform the bridge when animals are observed; identify their location and distance; and identify situations when seismic survey shutdowns, course changes, and speed reductions are needed to maintain specified separation distances designed to avoid take. Third, the data collected by MMOs about encounters will be used to refine mitigation measures, if needed. Fourth, standard operation procedures for aircraft (altitude requirements and lateral distance separation) are also designed to avoid disturbance of walruses and polar bears.

We conclude that any incidental take reasonably likely to occur as a result of carrying out any of the activities described under these regulations will have no more than negligible impacts on walruses and polar bears in the Chukchi Sea region, and we do not expect any resulting disturbances to negatively impact the rates of recruitment or survival for the Pacific walrus and polar bear populations. As described in detail previously, we expect that only small numbers of Pacific walruses and polar bears will be exposed to Industry activities. We expect that individual Pacific walruses and polar bears that are exposed to Industry activity will experience only short-term, temporary, and minimal changes to their normal behavior. These regulations will not authorize lethal take, and we do not anticipate any lethal take will occur.

Findings

We make the following findings regarding this action:

Small Numbers

The Service finds that any incidental take reasonably likely to result from the effects of the proposed activities, as mitigated through this regulatory process, will be limited to small numbers of walruses and polar bears relative to species abundance. In making this finding the Service developed a ''small numbers'' analysis based on: (a) The seasonal distributions and habitat use patterns of walruses and polar bears in the Chukchi Sea; (b) the timing, scale, and habitats associated with Industry activities and the limited potential area of impact in open water habitats, and (c) monitoring requirements and mitigation measures designed to limit interactions with, and impacts to, polar bears and walruses. We concluded that only a subset of the overall walrus population will occur in the specified geographic region and that a small proportion of that subset will encounter Industry operations. In addition, only a small proportion of the relevant stocks of polar bear and Pacific walruses will likely be impacted by Industry activities because: (1) The proportion of walruses and polar bears in the U.S. portion of the Chukchi Sea during the open-water season is relatively small compared to numbers of walruses and polar bears found outside the region; (2) within the specified geographical region, only small numbers of walruses or polar bears will occur in the open water habitat where proposed marine Industry activities will occur; (3) within the specified geographical region, the scope of marine operations is a small percentage of the open water habitat in the region; (4) based on monitoring information, only a portion of the animals in the vicinity of the Industry activities are likely to be affected; and (5) the required monitoring requirements and mitigation measures described below will further reduce impacts.

The number of animals likely to be affected is small, because: (1) A small

proportion of the Pacific walrus population or the Chukchi Sea and Southern Beaufort Sea polar bear populations will be present in the area of proposed Industry activities; (2) of that portion, a small percentage will come in contact with Industry activities; and (3) of those individuals that may come in contact with Industry activities, less than one-third are anticipated to exhibit a behavioral response that may rise to the level of harassment as defined by the MMPA.

Negligible Effects

The Service finds that any incidental take reasonably likely to result from the effects of oil and gas related exploration activities during the period of this rule in the Chukchi Sea and adjacent western coast of Alaska will have no more than a negligible effect, if any, on Pacific walruses and polar bears. We make this finding based on the best scientific information available including: (1) The results of monitoring data from our previous regulations (19 years of monitoring and reporting data); (2) the review of information generated in connection with listing the polar bear as a threatened species; (3) the analysis of the listing of the Pacific walrus as a candidate species under the ESA, and the status of the population; (4) the biological and behavioral characteristics of the species, which is expected to limit the amount of interactions between walruses, polar bears, and Industry; (5) the nature of oil and gas Industry activities; (6) the potential effects of Industry activities on the species, which will not impact the rates of recruitment and survival of polar bears and walruses in the Chukchi Sea region; (7) the documented impacts of Industry activities on the species, where nonlethal, temporary, passive takes of animals occur, taking into consideration cumulative effects; (8) potential impacts of declining sea ice due to climate change, where both walruses and polar bears can potentially be redistributed to locations outside the areas of Industry activity due to their fidelity to sea ice; (9) mitigation measures that will minimize Industry impacts through adaptive management; and (10) other data provided by monitoring activities through the incidental take program in the Beaufort Sea (1993 to 2011) and in the Chukchi Sea (1989 to 1996 and 2006 to 2011).

In making these findings, we considered the following:

(1) The distribution of the species (through 10 years of aerial surveys and studies of feeding ecology, and analysis of pack ice position and Pacific walrus and polar bear distribution);

(2) The biological characteristics of the species (through harvest data, biopsy information, and radio telemetry data);

(3) The nature of oil and gas Industry activities;

(4) The potential effects of Industry activities and potential oil spills on the species;

(5) The probability of oil spills occurring;

(6) The documented impacts of Industry activities on the species taking into consideration cumulative effects;

(7) The potential impacts of climate change, where both walruses and polar bears can potentially be displaced from preferred habitat;

(8) Mitigation measures designed to minimize Industry impacts through adaptive management; and

(9) Other data provided by Industry monitoring programs in the Beaufort and Chukchi seas.

We also considered the specific Congressional direction in balancing the potential for a significant impact with the likelihood of that event occurring. The specific Congressional direction that justifies balancing probabilities with impacts follows:

> If potential effects of a specified activity are conjectural or speculative, a finding of negligible impact may be appropriate. A finding of negligible impact may also be appropriate if the probability of occurrence is low but the potential effects may be significant. In this case, the probability of occurrence of impacts must be balanced with the potential severity of harm to the species or stock when determining negligible impact. In applying this balancing test, the Service will thoroughly evaluate the risks involved and the potential impacts on marine mammal populations. Such a determination will be made based on the best available scientific information [53 FR 8474, March 15, 1988; 132 Cong. Rec. S 16305 (October 15, 1986)].

We reviewed the effects of the oil and gas Industry activities on polar bears and walruses, including impacts from noise, physical obstructions, human encounters, and oil spills. Based on our review of these potential impacts, past LOA monitoring reports, and the biology and natural history of walruses and polar bears, we conclude that any incidental take reasonably likely to or reasonably expected to occur as a result of Industry activities will have a negligible impact on polar bear and Pacific walrus populations. Furthermore, we do not expect these disturbances to affect the annual rates of recruitment or survival for the walrus and polar bear populations. These regulations will not authorize lethal take, and we do not anticipate any lethal take will occur.

The probability of an oil spill from exploration activities that would cause significant impacts to walruses and polar bears appears to be low during the 5-year timeframe of these regulations. In the unlikely event of a catastrophic spill, we will take immediate action to minimize the impacts to these species and reconsider the appropriateness of authorizations for incidental taking through section 101(a)(5)(A) of the MMPA.

Our finding of ''negligible impact'' applies to incidental take associated with the oil and gas exploration activities as mitigated through the regulatory process. The regulations establish monitoring and reporting requirements to evaluate the potential impacts of authorized activities, as well as mitigation measures designed to minimize interactions with and impacts to walruses and polar bears. We will evaluate each request for an LOA based on the specific activity and the specific geographic location where the activities are projected to occur to ensure that the level of activity and potential take is consistent with our finding of negligible impact. Depending on the results of the evaluation, we may grant the authorization, add further operating restrictions, or deny the authorization.

Conditions are attached to each LOA. These conditions minimize interference with normal breeding, feeding, and possible migration patterns to ensure that the effects to the species remain negligible. A complete list and description of conditions attached to all LOAs is found at the end of this document in the changes to 50 CFR 18.118. Examples of conditions include, but are not limited to: (1) These regulations do not authorize intentional taking of polar bears or walruses or lethal incidental take; (2) for the protection of pregnant polar bears during denning activities (den selection, birthing, and maturation of cubs) in known denning areas, Industry activities may be restricted in specific locations during specified times of the year; and (3) each activity covered by an LOA requires a site specific plan of operation and a site specific polar bear and walrus interaction plan. We may add additional measures depending upon site specific and species specific concerns. We will analyze the required plan of operation and interaction plans to ensure that the level of activity and possible take are consistent with our finding that total incidental takes will have a negligible impact on polar bear and walruses and, where relevant, will not have an unmitigable adverse impact on the availability of these species for subsistence uses.

Further, because of our concerns over the HSWUA, we have determined that minimizing potential disturbance to walruses during the period of July through September, when they may be concentrated in large numbers and heavily utilizing this food rich environment, is necessary to ensure their continued contribution to the marine environment. Therefore, we have also determined that, for Industry activities such as seismic surveys and exploration drilling, it is unlikely that LOAs issued by the Service pursuant to the ITRs would authorize take from such activities in the HSWUA during times of high walrus use. As individual LOA applications are received, we will examine the proposed activities in light of the boundaries of the HSWUA, actual walrus distributions at that time, and the timing of the proposed activities. If the Service determines that the proposed activity is likely to negatively impact more than small numbers of walruses, we will consider whether additional mitigation and monitoring measures, including seasonal and spatial restrictions, could reduce any potential impacts to meet the small numbers and negligible impact standards. The Service will make those determinations on a case-by-case basis.

We have evaluated climate change in regard to polar bears and walruses. Although climate change is a worldwide phenomenon, it was analyzed as a contributing effect that could alter polar bear and walrus habitat and behavior. Climate change could alter walrus and polar bear habitat because seasonal changes, such as extended duration of open water, may preclude sea ice habitat use and restrict some animals to coastal areas. The reduction of sea ice extent, caused by climate change, may also affect the timing of walrus and polar bear seasonal movements between the coastal regions and the pack ice. If the sea ice continues to recede as predicted, it is hypothesized that polar bears may spend more time on land rather than on sea ice similar to what has been recorded in Hudson Bay, Canada. Climate change could also alter terrestrial denning habitat through coastal erosion brought about by accelerated wave action. The challenge will be predicting changes in ice habitat, barrier islands, and coastal habitats in relation to changes in polar bear and walrus distribution and use of habitat.

Climate change over time continues to be a major concern to the Service, and we are currently involved in the collection of baseline data to help us understand how the effects of climate change will be manifested in the Chukchi Sea walrus and polar bear populations. As we gain a better understanding of climate change effects on the Chukchi Sea population, we will incorporate the information in future actions. Ongoing studies include those led by the Service and the USGS Alaska Science Center to examine polar bear and walrus habitat use, reproduction, and survival relative to a changing sea ice environment. Specific objectives of the project include: An enhanced understanding of walrus and polar bear habitat availability and quality influenced by ongoing climate changes and the response by polar bears and walruses; the effects of walrus and polar bear responses to climate-induced changes to the sea ice environment on body condition of adults, numbers and sizes of offspring, and survival of offspring to weaning (recruitment); and population age structure.

Impact on Subsistence Take

Based on the best scientific information available and the results of harvest data, including affected villages, the number of animals harvested, the season of the harvests, and the location of hunting areas, we find that the effects of the exploration activities in the Chukchi Sea region will not have an unmitigable adverse impact on the availability of walruses and polar bears for taking for subsistence uses during the period of the rule. In making this finding, we considered the following: (1) Historical data regarding the timing and location of harvests; (2) effectiveness of mitigation measures stipulated by Service regulations for obtaining an LOA at 50 CFR 18.118, which includes requirements for community consultations and POCs, as appropriate, between the applicants and affected Native communities; (3) the BOEM/BSEE issued operational permits; (4) records on subsistence harvest from the Service's Marking, Tagging, and Reporting Program; (5) community consultations; (6) effectiveness of the POC process between Industry and affected Native communities; and (7) anticipated 5-year effects of Industry activities on subsistence hunting.

Applicants must use methods and conduct activities identified in their LOAs in a manner that minimizes to the greatest extent practicable adverse impacts on walruses and polar bears, their habitat, and on the availability of these marine mammals for subsistence uses. Prior to receipt of an LOA, Industry must provide evidence to us that community consultations have occurred and that an adequate POC has been presented to the subsistence communities. Industry will be required to contact subsistence communities that may be affected by its activities to discuss potential conflicts caused by location, timing, and methods of proposed operations. Industry must make reasonable efforts to ensure that activities do not interfere with subsistence hunting and that adverse effects on the availability of polar bear or walruses are minimized. Documentation of all consultations must be included in LOA applications. Documentation must include meeting minutes, a summary of any concerns identified by community members, and the applicant's responses to identified concerns. If community concerns suggest that Industry activities could have an adverse impact on the subsistence uses of these species, conflict avoidance issues must be addressed through a POC. The POC will help ensure that oil and gas activities will continue to not have an unmitigable adverse impact on the availability of the species or stock for subsistence uses.

Where prescribed, holders of LOAs must have a POC on file with the Service and on site. The POC must address how applicants will work with potentially affected Native communities and what actions will be taken to avoid interference with subsistence hunting opportunities for walruses and polar bears. The POC must include:

1. A description of the procedures by which the holder of the LOA will work and consult with potentially affected subsistence hunters.

2. A description of specific measures that have been or will be taken to avoid or minimize interference with subsistence hunting of walruses and polar bears, and to ensure continued availability of the species for subsistence use.

The Service will review the POC to ensure any potential adverse effects on the availability of the animals are minimized. The Service will reject POCs if they do not provide adequate safeguards to ensure that marine mammals will remain available for subsistence use.

The Service has not received any reports and is aware of no information that indicates that polar bears or walruses are being or will be deflected from hunting areas or impacted in any way that diminishes their availability for subsistence use by the expected level of oil and gas activity. If there is evidence during the 5-year period of these regulations that oil and gas activities are affecting the availability of walruses or polar bears for take for subsistence uses, we will reevaluate our findings regarding permissible limits of take and the measures required to

ensure continued subsistence hunting opportunities.

Monitoring and Reporting

The purpose of monitoring requirements is to assess the effects of industrial activities on polar bears and walruses, to ensure that take is consistent with that anticipated in the negligible impact and subsistence use analyses, and to detect any unanticipated effects on the species. Monitoring plans document when and how bears and walruses are encountered, the number of bears and walruses, and their behavior during the encounter. This information allows the Service to measure encounter rates and trends of bear and walrus activity in the industrial areas (such as numbers and gender, activity, seasonal use) and to estimate numbers of animals potentially affected by Industry. Monitoring plans are site-specific and dependent on the proximity of the activity to important habitat areas, such as den sites, travel corridors, and food sources; however, all Industry operators are required to report all sightings of polar bears and walruses. To the extent possible, monitors will record group size, age, sex, reaction, duration of interaction, and closest approach to Industry. Activities within the coast of the geographic region may incorporate daily watch logs as well, which record 24-hour animal observations throughout the duration of the project. Polar bear monitors will be incorporated into the monitoring plan if bears are known to frequent the area or known polar bear dens are present in the area. At offshore Industry sites, systematic monitoring protocols will be implemented to statistically monitor observation trends of walruses or polar bears in the nearshore areas where they usually occur.

Monitoring activities are summarized and reported in a formal report each year. The applicant must submit an annual monitoring and reporting plan at least 90 days prior to the initiation of an activity, and the applicant must submit a final monitoring report to us no later than 90 days after the completion of the activity. We base each year's monitoring objective on the previous year's monitoring results.

We require an approved plan for monitoring and reporting the effects of oil and gas Industry exploration, development, and production activities on polar bears and walruses prior to issuance of an LOA. Since production activities are continuous and long-term, upon approval, LOAs and their required monitoring and reporting plans will be issued for the life of the activity or until the expiration of the regulations, whichever occurs first. Each year, prior to January 15, we require that the operator submit development and production activity monitoring results of the previous year's activity. We require approval of the monitoring results for continued operation under the LOA.

Treaty Obligations

The regulations are consistent with the Bilateral Agreement for the Conservation and Management of the Polar Bear between the United States and the Russian Federation. Article II of the Polar Bear Agreement lists three obligations of the Parties in protecting polar bear habitat:

(1) ''Take appropriate action to protect the ecosystem of which polar bears are a part'';

(2) ''Give special attention to habitat components such as denning and feeding sites and migration patterns''; and

(3) ''Manage polar bear populations in accordance with sound conservation practices based on the best available scientific data.''

This rule is also consistent with the Service's treaty obligations because it incorporates mitigation measures that ensure the protection of polar bear habitat. LOAs for industrial activities are conditioned to include area or seasonal timing limitations or prohibitions, such as placing 1-mile avoidance buffers around known or observed dens (which halts or limits activity until the bear naturally leaves the den), building roads perpendicular to the coast to allow for polar bear movements along the coast, and monitoring the effects of the activities on polar bears. Available denning habitat maps are provided by the USGS.

Summary of Changes From the Proposed Rule

In preparing these final regulations for the Pacific walrus and polar bear, we reviewed and considered comments and information from the public on our proposed rule published in the **Federal Register** on January 9, 2013 (78 FR 1942). We also considered the analysis in our environmental assessment (EA). Based on those considerations, we are finalizing these regulations with the following changes from our proposed rule:

In this final rule, we have clarified:

(1) Numerical limitation on seismic and drilling operations;

(2) Geographic region subject to ITRs;

(3) Icebreaking and ice management issues;

(4) The definition and geographic delineation of Hanna Shoal as utilized by Pacific walruses;

(5) Special mitigation measures for coastal haulouts;

(6) Special mitigation measures for HSWUA;

(7) Spacing requirements for seismic vessels and exploratory drilling operations;

(8) Research studies and monitoring issues;

(9) The timing of activities;

(10) Helicopter height restrictions;

(11) The definition of a walrus group;

(12) Walrus Level B Harassment issues;

(13) Mitigation measures for vessel speeds;

(14) Treatment of polar bear critical habitat;

(15) Ice seal ESA listing; and

(16) Incentivizing new technology.

Summary of and Responses to Comments and Recommendations

During the public comment period, we requested written comments from the public in order to ensure that any final action be as accurate and as effective as possible. The comment period on the proposed ITRs opened on January 9, 2013 (78 FR 1942), and closed on February 8, 2013. During that time, we received 15 submissions from the public; these included comments on the proposed rule as well as the draft EA.

The Service received comments from the Marine Mammal Commission, State of Alaska, private companies, trade and environmental organizations, and the general public. We reviewed all comments received for substantive issues, new information, and recommendations regarding these ITRs and the draft EA. The comments on the proposed ITRs, aggregated by subject matter, summarized and addressed below, are incorporated into the final rule as appropriate. The Service has summarized and responded to comments pertaining to the draft EA in our final EA.

Response to Comments

1. Project Specific

Comment 1: Numerous commenters expressed general opposition to the promulgation of the ITRs.

Response: Language within section 101(a)(5)(A) of the MMPA requires the Service to allow the incidental taking of small numbers of marine mammals provided the Service has made certain determinations regarding the specified activity; simply choosing to not promulgate regulations is not consistent with these statutory requirements.

Comment 2: The ITRs appear to regulate the level of exploration activities that could be conducted in the Chukchi Sea to 1 per year; this is too restrictive and the level should be increased to consider multiple simultaneous operations.

Response: The Service does not regulate the level or type of exploration activities conducted by Industry. Instead as required by section 101(a)(5)(A) of the MMPA, the Service analyzes those activities associated with a request by a petitioner in considering potential impacts to Pacific walruses and polar bears for the purpose of promulgating regulations regarding the incidental take of these species. Specifically, we have based our take estimates for these two species on the types and levels of activities that have been described to us in AOGA's January 13, 2012, petition.

The petition identified one seismic activity per year for the 5-year regulatory period. However, the Service has the discretion in conducting its analysis to assess the potential impacts that more frequent activities may have on polar bears or Pacific walruses. We chose to analyze the potential impacts of two seismic operations on polar bears and Pacific walruses to make sure we did not underestimate inputs in our analysis; this was also based on the level of activities proposed in prior years. The text of this final rule has been updated to explain this analysis.

Comment 3: The Service provided no science-based rationale for the limit on the number of simultaneous operations.

Response: In most instances, the Service analyzes the potential effects of Industry activities in the geographic region based mainly on information presented in the petition. In this case the Service's analysis is based on an assessment of inputs from a greater number of annual operations than requested by the petitioners as previously explained. Based on this analysis, the Service has determined that issuing regulations for the incidental take of polar bears and walruses that may result from Industry activities is appropriate. In issuing the regulations, the Service is neither authorizing nor restricting the actual activities that may occur. Rather, it is evaluating the impacts from activities that may warrant incidental take authorization.

Comment 4: The regulations should identify and include the specific types and numbers of activities upon which the Service has made its small numbers and negligible impacts findings.

Response: As discussed in previous regulations (see 73 FR 33212; June 11, 2008), these regulations provide petitioners an overall ''umbrella'' set of guidelines which, when followed, allow certain oil and gas exploration activities to proceed in such a manner that minimizes the potential incidental take of polar bears and Pacific walruses. This ensures that no more than small numbers will be taken, there is no more than a negligible impact on these species, and there is no unmitigable impact on subsistence use of these species. To that end, the Service has described the general types of activities to be authorized, as requested by the petitioners; the projected scale of each activity; and the anticipated impacts that could occur during the specified time period. The regulations acknowledge that in the planning phases, most projects contain some element of uncertainty. Consequently, in addition to requiring certain mitigation measures common to all projects, a separate LOA will be required for each specific survey, seismic, or drilling activity. This allows each specific LOA request to be evaluated for additional mitigation methods over and above those required in the umbrella guidelines. The regulations set forth in this final rule specify those mitigation measures required for all oil and gas activities, as well as those mitigation measures that may be required depending on the type or location of the activity. Further, these regulations describe under what conditions the various types of mitigation measure will be required.

Comment 5: The regulations should refrain from authorizing taking of marine mammals incidental to in-ice surveys until the Service has either (1) proposed regulations to authorize such taking, given the public an opportunity to comment on those regulations, and issued final regulations that specifically authorize such taking or (2) issued an alternative authorization for those activities (e.g., an incidental harassment authorization).

Response: The petitioner did not request in-ice seismic programs. As a result, the regulations do not authorize incidental take associated with them.

Comment 6: The geographic region identified in the proposed rule does not include the full area set forth in AOGA's petition, or alternately offer an explanation as to why it modified the map.

Response: In the absence of specific information about where activities are projected to occur in this area, we analyzed the effects of potential activities in the geographic region of the prior regulations (73 FR 33212; June 11, 2008), including the NPR–A. We will address any activities proposed for those areas outside the geographic region of these ITRs on a case-by-case basis, considering the use of other potential management tools under provisions of the MMPA other than section 101(a)(5)(A) to minimize take of polar bears and walruses.

Comment 7: The Service does not identify ''specific geographic regions'' within which Industry activities will occur.

Response: We disagree. The specific geographic region is identified as the Chukchi Sea, including near shore and coastal land areas, and is described in these final regulations in the Description of Geographic Region section. This description of the geographic region is the same as that set forth in our proposed regulations.

Comment 8: The Service did not analyze the impact of Industry activities in all areas where those activities will occur.

Response: We disagree. The Service's analysis encompassed the potential impacts of the Industry activities as identified in the petitioners' request. This analysis was unique to the specified geographical region as discussed above.

Comment 9: The Service may not authorize takes of any marine mammals in the Chukchi Sea until it requires Industry applicants to disclose more specific geographical regions in which they intend to operate during the course of the next 5 years, makes that information available to the public, and provides an opportunity for the public to comment.

Response: By issuing the regulations here, the Service has considered the effects of Industry activities, as set forth in the petition, in the geographic area described previously. Based on this information and projected effects of these activities, the Service has determined that no more than small numbers will be taken, the activities are likely to have a negligible impact on polar bears and Pacific walruses, the activities and will not have an unmitigable adverse impact on the availability of those species for subsistence use. Based on this determination, individual LOAs may be requested and granted for activities based on a more specific description of the nature, location, and timing of the activities provided during the LOA application process.

Comment 10: The Service should provide a reasoned explanation for including the coverage of the Barrow Gas Fields within the final rule when it was not requested by the petitioners.

Response: We agree. The petition did not specifically identify the Barrow Gas Fields in its request to the Service for the issuance of ITRs. However, the petition did include a description of this area as part of its request. Additionally, a portion of the Barrow Gas Fields are similarly described in our ITRs issued on August 3, 2011, for the Beaufort Sea (76 FR 47010), while the remainder is located in the Chukchi Sea geographic region. Therefore, as part of this analysis, the Service opted to include the Barrow Gas Fields in the event that LOAs for activities on the Chukchi Sea side of the field are requested.

Comment 11: The Service should include accurate descriptions of additional types of surveys, such as 4D, multi-azimuth, full-azimuth, and/or ocean bottom seismic surveys in the proposed rule or EA so that they are included in the scope of activities considered.

Response: We agree, and note that all activities described and requested within AOGA's petition were analyzed in our proposed rule as well as these final regulations, and they are discussed in the Description of Activities section.

Comment 12: The estimated airgun array size (4,000 cubic inches) should be increased to 6,000 cubic inches to better reflect potential activities and to reflect the range of volumes currently used by Industry.

Response: While Industry and government analysis standards may be 6,000 cubic inches, the petitioners only described estimated gun arrays of up to 4,000 cubic inches in the petition. Thus, the Service only considered the use of airguns up to 4,000 cubic inches.

Comment 13: The ITRs should not authorize Arctic ice-breaking due to the concern of the effects ice breaking may have on climate change.

Response: These regulations do not allow ''Arctic ice-breaking'' as the commenter suggests. This rule evaluates the potential incidental take of polar bears and Pacific walruses by a proposed group of activities and provides a process by which an authorization may be obtained for such take. The petitioners did not propose ''ice-breaking'' as an activity, but do propose ''ice management,'' which may include some ice-breaking. As proposed by the petitioners, ice management would consist of actively pushing the ice off its trajectory with the bow of the ice management vessel, but some ice-breaking could be required for the safety of property and assets, such as a drill rig. This was considered and analyzed in the development of these ITRs.

2. Project Impacts

Comment 14: The Service should consider the cumulative impacts of exploration, including ice-breaking, as a climate hazard, where sea ice will be broken with icebreaker vessels deflecting ice floes from drill rigs.

Response: The scope of climate change goes beyond this regulatory analysis, which is to determine whether the total level of incidental take as a result of the exploration activities proposed by the oil and gas Industry will affect only small numbers of polar bears and walruses, have a negligible impact on these animals, and have no unmitigable adverse impact on subsistence use of these species. For this analysis, the only ice breaking we analyzed is that which may occur if a large floe needed to be deflected from Industry equipment (including ships and drilling platforms), and whether breaking up that floe would be necessary for success and safety. For example, in 2012, ice management was required during a total of 7 days from August 31 to September 13, and was limited to nine discrete isolated events. Of these nine events, ice was broken apart only two times. Further, if ice floes are too large, the drill rig will cease operations, secure the site, release the anchors, and move from the site until the floe has passed, as occurred in 2012, at the Burger A prospect, where the drill ship was moved off-site for 10 days to avoid ice.

Comment 15: The Service needs to consider the greenhouse gas emissions (GHG) involved in exploration activities in the Arctic region.

Response: While the Service recognizes the primary threat to the continued existence of the polar bear is loss of sea ice habitat due to climate change, and loss of sea ice habitat is also of concern for the Pacific walrus, the Service addressed its position on GHG in a final rule establishing a special rule under section 4(d) of the ESA for the polar bear (78 FR 11766; February 20, 2013). In that rule, the Service finds that while GHG emissions are clearly contributing to climate change, the comprehensive authority to regulate those emissions is not found in the statutes that govern the management of marine mammals, such as the MMPA or the ESA. The challenge posed by climate change and its ultimate solution is much broader. Federal and State governments, Industry, and nonprofit organizations are exploring ways to collectively reduce GHG emissions as we continue to meet our nation's energy needs.

The Service is working in other arenas to address the effects of climate change on polar bears. For example, the Service's recently released ''Rising to the Urgent Challenge: Strategic Plan for Responding to Accelerating Climate Change'' (*http://www.fws.gov/home/climatechange/pdf/CCStrategicPlan.pdf*) acknowledges that no single organization or agency can address an environmental challenge of such global proportions without allying itself with others in partnerships across the nation and around the world. Specifically, this Strategic Plan commits the Service to (1) lay out our vision for accomplishing our mission to ''work with others to conserve, protect, and enhance fish, wildlife, and plants and their habitats for the continuing benefit of the American people'' in the face of accelerating climate change and (2) provide direction for our own organization and its employees, defining our role within the context of the Department of the Interior and the larger conservation community.

Comment 16: The Service should consider potential impacts to under-ice phytoplankton algal blooms in the Chukchi Sea resulting from ice-breaking activities.

Response: Because activities will be conducted primarily during the open-water period, well after any bloom may occur, potential impacts to the under-ice algal bloom due to ice-breaking are expected to be insignificant.

Comment 17: This regulation could negatively impact other migrating and local species integral to the ecosystem.

Response: In this rule, the Service analyzed incidental take and potential impacts of potential Industry activities on Pacific walruses and polar bears. These regulations do not address the other species potentially affected by Industry activities; those effects are described in other agency documents, such as BOEM's Chukchi Sea Planning Area, Oil and Gas Lease Sale 193 Final Environmental Impact Statement (FEIS). However, the specified period of open-water operations and affiliated mitigation measures are designed to account for the bulk of the walrus migration and will likely reduce conflicts with other local and migrating marine mammals and birds.

Comment 18: Current noise conditions should be documented in the arctic marine environment.

Response: We agree. However, documenting noise conditions in the arctic is a large, complex, and expensive task. Ambient noise, vessel traffic noise, seismic survey noises, drilling noise, ice-management noise, etc., have been documented since 2006, through

ongoing cooperative studies. A study investigating baseline acoustic and environmental noise in the Chukchi Sea is currently underway and will continue under these regulations.

Comment 19: One commenter expressed concern that the cumulative addition of any potential fatal impacts from oil and gas Industry activities will push both species closer to extinction.

Response: The petition did not include, and these regulations do not authorize, lethal incidental take of Pacific walruses or polar bears. Nevertheless, the Service has considered a potential for accidental death to an animal. For example, a polar bear did die in the Southern Beaufort Sea in 2011, as a result of Industry activities. Based on our analysis, we have determined that the likelihood of a lethal take is small and the impact to polar bear and Pacific walrus populations is negligible The Service is only authorizing nonlethal, unintentional incidental take.

Comment 20: The Service did not model for an oil spill in the Chukchi Sea. Had the Service modeled the impacts of a very large oil spill in the Chukchi Sea, the take estimates for the permitted activities would have been much greater, calling into question its small numbers and negligible impact determinations.

Response: We acknowledge that an oil spill is a possible outcome of Industry activity, and for this reason we have analyzed and discussed potential spills and their impacts to Pacific walruses or polar bears (see Potential Impacts of Waste Product Discharge and Oil Spills on Pacific Walruses and Polar Bears). For our evaluation, we relied on the BOEM oil spill models described in the BOEM Lease Sale 193 EIS and Supplemental EIS, and based on our analysis we conclude that the probabilities of a large oil spill are low. Should such a spill occur, oil will impact any animals that come in contact with it; therefore, we are currently working on developing an oil spill risk assessment model specific to polar bears in the Chukchi Sea as well as updating our oil spill response plan for Pacific walrus.

Comment 21: One commenter stated that even if the probability of a blowout and very large oil spill in the Chukchi Sea is low, the magnitude of the consequences of such a spill make it worthy of consideration.

Response: The Service considered the impacts of a very large spill to Pacific walruses and polar bears (see Potential Impacts of Waste Product Discharge and Oil Spills on Pacific Walruses and Polar Bears). To date, there have been no major spills associated with exploration activities in either the Beaufort or Chukchi Seas. Large spills (>1,000 bbls) have historically been associated with production facilities or at pipelines connecting wells to the pipeline system. It is anticipated that during the authorized exploratory activities, adherence to the current regulatory standards and practices for prevention, containment, and clean-up will minimize potential adverse impacts from oil spills. In the unlikely event of a very large spill, we will reassess the impacts to the polar bear and walrus populations and reconsider the appropriateness of authorizations for taking through this regulation under section 101(a)(5)(A) of the MMPA.

Comment 22: One commenter stated that a stronger oil spill response plan should be developed and more research needs to be conducted on information gaps before activities are permitted.

Response: Research efforts that may serve to enhance our understanding of the potential response needs in the event of an oil spill event are ongoing. For example, there are currently numerous research projects investigating many of the ecosystem components of the Chukchi Sea, such as the Chukchi Sea Environmental Studies Program sponsored by the Industry, ecosystem studies funded by BOEM Environmental Studies Program, walrus and polar bear research conducted by USGS and the Service, and the Aerial Surveys of Arctic Marine Mammals project conducted by NMFS. The Service has used and will continue to use both preliminary and final results of this research in the development of ITRs when and where applicable. Also, the Service continues to contribute to the oil spill response plans developed by the USCG, which are continuously being improved as new information, technology, and infrastructure becomes available.

Comment 23: With high winds and rough weather, it is quite easy for waste products to leave the vessels and quickly pollute the surrounding environment. This could cause further damage and interruption to the ecosystem and the life cycle of polar bears.

Response: It is beyond the authority of the Service and the MMPA to regulate potential accidental waste product discharge into the environment. Waste product discharge into the environment is regulated under other laws and permits, such as provisions of the Clean Water Act (33 U.S.C. 1251 et seq.) and the Oil Pollution Act (33 U.S.C. 2701 et seq.), among others. We have, however, taken such an eventuality into account in our small spill analysis and have determined that there is a low probability of such an occurrence. We have further determined that any potential impacts will affect only a small number of polar bears and Pacific walruses, will have a negligible impact on these species, and will not have an unmitigable adverse impact on their availability for subsistence uses.

3. Mitigation and Monitoring

Comment 24: The Service should reconsider seasonal mitigation procedures, including seasonal exclusions, that will be required near coastal haulouts and, specifically, near the Hanna Shoal area because they may result in unnecessary and burdensome exclusions from areas located near purchased leases.

Response: The general protective measures associated with these ITRs include limitation on Industry activities around walruses on land or ice and are intended to prevent mortality and level A harassment (potential to injure) resulting from panic responses and intra-specific trauma (e.g., trampling injuries by large groups of animals). These standards are based upon the best available information concerning walrus flight responses to vessels and aircrafts, and are consistent with current guidelines in other parts of Alaska. The potential for intra-specific trauma is greatly reduced when animals are encountered in the water. Although these mitigation measures are also expected to help reduce incidences of Level B (potential to disturb) harassment, they are not intended to completely eliminate the possibility of disturbances. Required monitoring during operations is expected to contribute data regarding flight responses, which will be used to evaluate the efficacy of these buffer areas in future impact assessments.

Additionally, we recognize that the Hanna Shoal area is an important feeding area for Pacific walruses regardless of sea ice presence or not. For example, telemetry studies indicate that animals will travel to the region even when there is no sea ice to haulout on, and once feeding bouts are complete, the animals will return to shore-based resting areas. This ensures continued, undisturbed access to this highly productive feeding area and is consistent with our determination of minimal impacts to the overall health and well-being of the Pacific walrus, where any potential impacts will affect only small numbers of walruses, will have a negligible impact on them, and will not have an unmitigable adverse

impact on their availability for subsistence uses.

Comment 25: The Service should define the Hanna Shoal referenced in the rule.

Response: We agree with this comment, and text has been added to the regulations.

Comment 26: Several commenters wanted further clarification on the provisions for seasonal restrictions and mitigation measures on oil and gas exploration and support activities near coastal haulout areas and in the travel corridor between Hanna Shoal and those areas.

Response: Walruses occupying coastal haulout areas along Alaska's Chukchi Sea coast are protected from disturbances through a variety of measures. Currently, the Service works in collaboration with the Federal Aviation Administration (FAA) to establish seasonal over-flight restrictions, and with the USCG to establish marine buffer areas to coastal walrus haulouts throughout Alaska. Through general guidance on how to operate around haulouts and temporary closures, these buffer areas help to protect and minimize disturbance to the haulouts. The flight restrictions and approach guidelines for marine vessels operating near coastal walrus haulouts set forth in these regulations are consistent with those in place in other areas (e.g., Bristol Bay) where coastal walrus haulouts develop. When a coastal haulout develops, the Service works with the FAA and USCG to establish airspace closures and marine buffer areas around the haulout. Haulout occupancy is monitored in collaboration with the NSB, the Alaska Department of Fish and Game, the NMFS, and local communities. These restrictions and monitoring remain in place until the haulout disbands, typically by mid-October. These restrictions have proven to be effective at mitigating disturbance events that can result in incidental injury and mortality.

Satellite telemetry studies of walruses occupying the eastern Chukchi Sea (Jay *et al.* 2012) indicate that most animals are utilizing a haulout area 4 miles (7.4 km) north of the coastal community of Point Lay. In addition to existing seasonal flight restrictions and marine buffer areas specific to coastal walrus haulouts, Industry-associated vessels and aircraft are restricted within an area of Ledyard Bay that is designated critical habitat for the spectacled eider (66 FR 9146; February 6, 2001); we refer to this area as the Ledyard Bay Critical Habitat Unit (LBCHU), and it extends seaward out approximately 40 miles (74 km) from the Point Lay haulout site. Although the operating restrictions in the LBCHU are intended primarily to provide protection to spectacled eiders, they also effectively serve to establish a protective buffer area from Industry activities at the Point Lay walrus haulout, and their migratory routes to offshore feeding areas. Telemetry data suggest that most walrus activity occurring near the Point Lay walrus haulout occurs in August and September in an area encompassed by LBCHU. Aircraft and marine vessels are restricted in the LBCHU between July 1 and November 15.

Industry activities authorized under these ITRs are also restricted within a 40-mile (74-km) radius of all coastal communities along the Chukchi Sea coast (including the community of Point Lay), unless expressly provided for in a POC. Although the intent of this restriction is to prevent interference with traditional marine mammal hunting activities, it also provides protection to walruses hauled out onto land or migrating through areas near the communities. The Service will review any request to operate within these defined subsistence buffer areas for consistency with our small numbers determination, and our finding that authorized activities will have a negligible impact on polar bears and walruses, and will not have an unmitigable adverse impact on the availability of these species for taking for subsistence uses.

Comment 27: The Service should do more to affirmatively protect the Hanna Shoal area from any activities that could disturb walruses from prohibiting all oil and gas activities on Hanna Shoal to creating time/place restrictions and an exclusion zone around the shoal that precludes activity that could disturb walrus use of the shoal.

Response: The separation distances described in the Response to Comment 26 will help mitigate impacts to walruses when at Hanna Shoal and when moving between Hanna Shoal and coastal haulouts. In the future, the cooperative studies to define important walrus areas within the Hanna Shoal area will inform our management of the area. However, to limit disturbance to walruses and to increase the effectiveness of the MMPA provisions and protect coastal haulouts, the Service works with BOEM, FAA, USCG, the State of Alaska, the NSB, and local communities to limit disturbances at haulouts. In addition, the Service's Office of Law Enforcement investigates reports of potential MMPA violations when and where they occur.

We do not anticipate issuing LOAs for certain Industry activities in the HSWUA during times of high walrus use in the 5-year regulatory period. As individual LOA applications are received, we will examine the proposed activities in light of the boundaries of the HSWUA, actual walrus distributions at that time, and the timing of the proposed activities. If the Service determines that the proposed activity is likely to negatively impact more than small numbers of walruses, we will consider whether additional mitigation and monitoring measures, including seasonal and spatial restrictions, could reduce any potential impacts to meet the small numbers and negligible impact standards. The Service will make those determinations on a case-by-case basis.

However, to protect the area effectively and consistently we need to explicitly define the boundaries of the area. As noted above, we have defined a HSWUA based on areas most important to walruses, as described earlier in this document.

Comment 28: The 15-mile exclusion zone associated with open-water operations is a concept for penetration seismic operations developed by BOEM (formerly MMS) to minimize interference among operators. However, if there is a biological reason for this exclusion zone, the proposed rule should reference the source information.

Response: As the commenters noted, the 15-mile exclusion zone was, in part, originally a BOEM stipulation for separation of seismic operations. As noted in the Final Environmental Impact Statement (EIS) for the Chukchi Sea Planning Area (OCS EIS/EA MMS 2007–026, May 2007), mitigation measures such as the 15-mile exclusion zone put in place for future exploration activities contributed to the protection of walruses and their continued availability to subsistence hunters (OCS EIS/EA MMS 2007–026 page IV–147).

Based on our best professional judgment, we agree and find that the 15-mile buffer will ameliorate potential impacts to walrus by ensuring a corridor for walrus to transit without experiencing take caused from seismic or drill activities. Seismic surveys have the potential to cause temporary or permanent hearing damage, mask underwater communications, and displace animals from preferred habitat (Richardson *et al.* 1995; Kastak *et al.* 2005; NRC 2003, 2005). We have determined that the biological benefits of a 15-mile separation of activities include: Reduction of the potential for hearing damage; reduction of potential noise density in a single area while allowing routes and areas for walruses to exit an area; reduction of the

potential number of animals exposed to multiple activities simultaneously, or in sequence within a short period of time, thus reducing the potential for taking of marine mammals by disturbance, allowing for uninterrupted underwater vocal communications, reducing the cumulative effects of operations that are in close proximity to each other and walruses, and reducing the potential for seismic surveys to interfere with subsistence hunters. We have, therefore, determined that it is important, effective, and efficient to include this 15-mile exclusion zone as a part of our mitigation measures.

This conclusion is consistent with the benefits attributed to cetaceans by a 15-mile buffer (see Supplemental draft EIS addressing effects of oil and gas operations in the Arctic, NOAA 2013). Further, because the requirement of a 15-mile buffer has been in place since publication of the 2008 Chukchi Sea ITRs and is already required by BOEM for operational reasons, we do not anticipate it will add a substantial burden.

Comment 29: One commenter disagreed with the Service's characterization of ''ice scouting'' as a mitigation measure.

Response: We are not requiring ice scouting as a potential mitigation measure rather, our intent is to require additional mitigation measures for the activity of ice scouting, if necessary, to minimize potential impacts to walruses or polar bears. For example, a mitigation measure of ice scouting could be a vessel setback from any animals observed on the ice. Although ice scouting is primarily an operational activity within the broader exploratory programs, it does have the potential to trigger mitigation measures. MMOs are on all ice scouting vessels, and vessels are often requested to reduce speed and alter course to maintain separation with walruses and polar bears when scouting ice. In addition, because walruses and polar bears are closely associated with the ice pack, ice scouting is valuable for identifying floes that harbor animals and providing information for operators of support vessels, aircraft, and drill rigs to avoid them.

Comment 30: Two commenters requested clarification of the intent of our requirement that Industry ''track animals.'' The commenters indicated that physically tracking animals, whether by vessel, aircraft, or telemetry equipment, can increase harassment. The commenters requested that the rule clarify that qualified individuals should only ''observe'' Pacific walruses and polar bears opportunistically and that the rule not require that mammals be followed for the purposes of observation.

Response: The only way to determine the longer-term impacts of Industry activities on marine mammals is to monitor impacts in some manner. This is important in assessing whether Industry activities meet the negligible impact requirement under the MMPA. Monitoring programs currently detect animals at the surface in proximity to vessels to initiate mitigation measures. Monitoring programs also document some of the immediate reactions of animals in proximity to Industry activities. However, we do not know the longer-term response of animals. Both of these types of data will inform the determination of whether there is only a negligible impact as required under the MMPA. To estimate longer-term impacts, there is a need to be able to monitor or ''track'' animals after exposure to any given activity in some fashion. That being said, we see this as a joint cooperative process between Industry and the regulatory agencies. When opportunities arise, we should take advantage of them to further our understanding of impacts to animals and address these information gaps. The inclusion of ''tracking animals'' in the monitoring and mitigation measures is to provide a mechanism by which the Service may work with Industry to accomplish this goal. Any such studies would need to be authorized under an appropriate scientific research permit.

Comment 31: The proposed rule includes a number of new mitigation and monitoring provisions that are either not included in current (or previous) ITRs for the Chukchi Sea.

Response: The Service recognizes that new or adjusted mitigation and monitoring has been included in these regulations and has added clarifying text to the measures to better explain our reasoning for including these new measures. It is the Service's mandate to manage and conserve our trust species, and our understanding of potential impacts has evolved as new information has become available regarding marine mammals and the magnitude of Industry activities. We have and will continue to adjust mitigation measures to help minimize impacts to walruses and polar bears. For example, the 3,000-ft aircraft minimum altitude restriction near coastal walrus haulouts is a modification of a previous mitigation measure (1,000-ft altitude and 0.5 mi lateral distance) based on new information since the time of the last regulations. Specifically, we have found that flight altitudes of 2,000 ft disturb land-based walrus haulouts (USFWS Administrative Report, R7/MMM 13–1, page 55); we anticipate that disturbance events will be reduced by increasing the minimum altitude over the haulout by another 1,000 ft to 3,000 ft while maintaining the 0.5 mi lateral distance separation. The new and adjusted mitigation and monitoring provisions help ensure that the negligible impacts standard of the MMPA requirement is met.

Comment 32: The Service should continue to implement the ½-mile separation requirement between Industry activities and Pacific walruses, as stated in current regulations, rather than expanding it.

Response: The Service is continuing to implement the ½-mile restriction for walruses in the water and on sea ice. The Service has modified the distance restriction for vessels operating near occupied coastal haulouts from ½ mile to 1 mile. New information indicates that the 1-mile separation is needed near coastal haulouts to avoid disturbing animals while at the coastal haulouts, particularly for vessels 100 feet or more in length. We have based this determination, in part, on direct observations made by haulout monitors stationed at coastal walrus haulouts in Bristol Bay, who in turn, noted responses of walruses to passing vessels (Jonathon Snyder, USFWS, 2012, pers. comm.). The proposed 1-mile buffer area is anticipated to significantly reduce the potential for haulout disturbances and mortalities. Additionally this buffer zone is consistent with, though less restrictive than, State of Alaska regulations (5 AAC 92.066) establishing a 3 mile buffer zone around the ''Walrus Islands State Game Sanctuary.'' By adjusting our protective measures to meet the evolving requirements of walrus management, we seek to reduce stampede events, which in turn result in walrus injury or mortality (Fay and Kelly 1980; Ovsyanikov *et al.* 1994, 2008; Kochnev 1999, 2006; Kavry *et al.* 2006, 2008).

Comment 33: The Service should specify in its regulations mitigation measures that will be required for drilling operations, shallow hazards surveys, other geophysical surveys, and geotechnical surveys.

Response: To the best of our ability, the Service has discussed and specified a suite of mitigation measures that will be used to mitigate incidental take of polar bears and Pacific walruses. The Service believes that the mitigation and monitoring measures identified in the rule encompass the overall suite of measures that are necessary to ensure the activities affect only small numbers of polar bears and walruses, have no more than a negligible impact on the

stocks, and will not have an unmitigable adverse impact on the availability of these species for subsistence uses. When a request for an LOA is made, the Service will determine which of the mitigation and monitoring measures will be necessary for the particular activity based on the details provided in the request. Through the LOA process, the Service will examine the siting and timing of specific activities to determine the potential interactions with, and impacts to, polar bears and walruses and will use this information to prescribe the appropriate mitigation measures to ensure the least practicable impact on polar bears and walruses, and on subsistence use of these species. In addition, the Service will review monitoring results to examine the responses of polar bears and walruses to various exploration activities and to adjust mitigation measures as necessary. We will also consider adjusting monitoring methodologies and mitigation measures as new technologies become available and practical.

Comment 34: The Service needs to strictly regulate and monitor all activities, including oil and gas exploration activities in the Chukchi Sea and adjacent coast of the United States, for the purposes of ensuring that Industry activities do not harm polar bears and walruses, and in instances where some impact cannot be avoided, to minimize such harm to a negligible level.

Response: The regulation of activities, including oil and gas activities, fall under a number of appropriate jurisdictions, including permitting by BOEM, BSEE, and BLM, depending on the location of the activity. The Service will issue LOAs for Industry activities that are consistent with these final regulations. The Service has determined that the monitoring and mitigation measures described in the regulations ensure that Industry activities will only affect small numbers of polar bears and walruses, will have only negligible impact on the stocks of polar bears and walruses, and will not have an unmitigable adverse impact on the availability of these species for subsistence uses. The Service does and will continue to play a key role in monitoring, and where appropriate, regulating such activities to ensure disturbance is minimized.

Comment 35: Commenters suggested increasing the length of the time period for open-water operations, seismic, and drilling programs by: (1) Allowing for an earlier beginning of the operational period prior to July 1; (2) extending the end date to December 31; and (3) allowing year-round activities in the marine environment. Commenter stated that adding specific criteria regarding the seasonal ice conditions and distribution information allowed for such extensions.

Response: The July 1 start date was specified to ensure that the majority of walruses utilizing the geographic area covered by these regulations will be out of the active seismic and drilling areas prior to initiation of these activities. In most years, sea ice will be rare in the geographic region by July 1, and walruses will either be in other areas of the Chukchi Sea where ice occurs or at coastal haulouts. In those rare years when ice and walruses may remain after July 1 in areas of Industry activities, mitigation measures will be implemented to minimize the take of animals should activities occur near ice. In addition to walrus considerations, some coastal communities, e.g., Point Lay, have requested that operations do not begin before July 1 to avoid conflicts with subsistence activities.

Operators can request a variance to enter the geographic region prior to July 1. The Service will analyze any requests for variances based primarily on the location and numbers of walruses in the transit area, as well as ice locations. Because the timing of the walrus migration varies from year to year and is dependent on sea ice conditions at that time, it is unlikely that we will be able to issue any variances until the actual conditions in any given year are fully understood. Likewise, the Service could review variance requests for late season extensions. The Service maintains the ability to allow for a variance for a change in timing of industrial activities based on biological and environmental conditions. A variance will be addressed with Industry activities on a case-by-case basis.

Comment 36: The Service should provide specific criteria regarding the seasonal ice conditions and distribution information that will allow for the issuance of exemptions to restrictions on (1) activities during the open-water season or (2) transit of operational or support vessels through the Chukchi Sea prior to July 1. Those criteria will also be needed to determine when to apply seasonal restrictions on oil and gas operational and support activities near coastal haulout areas and in the travel corridor between Hanna Shoal and those areas.

Response: Our LOAs apply specific mitigation measures to specific activities and the Service does have the flexibility, when appropriate, to respond to changing sea ice conditions. For example, if sea ice and walruses are not found to be in an area where exploration activities are to occur prior to July 1, the Service may issue a variance on an LOA that allows for such activities to commence. The Service believes allowing activities to occur earlier could be advantageous, as it will increase the likelihood that Industry will be able to meet its annual goals and reduce pressure to achieve those goals as November 30 draws closer. Because any such variance, or other action, requires a real-time assessment of walrus densities, weather conditions, and potential changes in conditions, which in turn, are based on actual ice dynamics, the Service does not believe a list of potential exceptions will be beneficial to the regulated public.

Comment 37: The proposed rule imposes a 3,000-ft height restriction on helicopters within 1 mile of walrus groups observed on land. This restriction is new, and is not explained in the proposed rule.

Response: This mitigation measure has been in effect for the last 3 years, but was not described in the previous rule. This mitigation measure is necessary to protect coastal haulouts, and text has been added to this final regulation to further explain this measure.

Comment 38: Two commenters requested that the Service exempt unmanned aerial systems (UASs) from the requirements in the ITRs pertaining to this type of aircraft and suggested that UAS may be used to monitor walruses and/or polar bears.

Response: The Service does not regulate the use of UASs. The FAA is responsible for that activity. We will not exempt UASs from aerial requirements until more information is available on the potential for these aircraft to cause disturbance to Pacific walruses, especially those in aggregations, and polar bears. Further, the Service recognizes that UASs vary greatly in size, configuration and potential uses, and the potential for an aircraft to disturb marine mammals will likewise vary; therefore, a blanket exemption is not prudent at this time. The use of UASs will have to undergo rigorous evaluations and testing before they can be approved to monitor walruses or polar bears. Once more information is known, exceptions may be possible based on multiple factors, such as the size of the UAS, flight distances to animals, the reaction of the animals to the UAS, and the need to be in the vicinity of animals.

Comment 39: One commenter stated that the approval of an interaction plan should be eliminated or the rule needs

to explain who must approve the plan and how this approval is to be obtained.

Response: The Service disagrees. The requirement for an approved polar bear and/or Pacific walrus interaction plan has existed for many years in prior ITRs for both the Chukchi and Beaufort Seas, and has proven to be a highly effective tool for avoiding, minimizing, monitoring, and reporting interactions between oil and gas activities and personnel and polar bears and Pacific walruses. The Service considers such interaction plans an important and mandatory component for any request for an LOA. Interaction plans are reviewed and approved by the Service as part of the process for a request for an LOA. The Service considers this process clear as described in the regulations (see 50 CFR 18.118(a)(1)(iii)).

Comment 40: The Service should use the term ''designated'' MMOs, rather than ''dedicated'' MMOs.

Response: 50 CFR 18.118(a)(1)(ii) states that ''Holders of Letters of Authorization must designate a qualified individual or individuals to observe, record, and report on the effects of their activities on polar bears and Pacific walruses.'' Section 18.118(a)(2)(i) states that ''Operational and support vessels must be staffed with dedicated marine mammal observers to alert crew of the presence of walruses and polar bears and initiate adaptive mitigation responses.'' The term ''dedicated'' is not merely a semantic interpretation of the duties of MMOs. When an individual is trained as a dedicated MMO their dedicated duties are to: (1) Alert crew of the presence of walruses and polar bears; (2) initiate adaptive mitigation responses; and (3) carry out specified monitoring activities identified in the marine mammal monitoring and mitigation plan necessary to evaluate the impact of authorized activities on walruses, polar bears, and the subsistence use of these subsistence resources. The MMOs must have completed a marine mammal observer training course approved by the Service. In addition, they should not have others duties on the vessel that may create a conflict of interest, e.g., the captain of the vessel should not also be an MMO.

Comment 41: One commenter felt it was burdensome to add a monitor on-site if dedicated MMOs are on-site.

Response: The Service disagrees. The Service maintains that as a stipulation contained within any LOA issued under this rule, we may require a monitor on the site of the activity or onboard drillships, drill rigs, aircraft, icebreakers, or other support vessels or vehicles to monitor the impacts of Industry's activity on polar bears and Pacific walruses. Such a monitor will be designated at the discretion of the Service and will be independent of any MMOs. For example, a Service law enforcement agent, wildlife biologist, or regulatory specialist may be designated to monitor a situation depending upon the circumstances. Given the significant expense, logistics, and technology required to conduct oil and gas exploration in the Chukchi Sea, the Service fails to see how the additional presence of a monitor will be burdensome.

Comment 42: In light of the knowledge gained in the past 5 years, the Service should reconsider which mitigation measures and monitoring requirements are absolutely necessary.

Response: The Service evaluated the request for this rule based on the best available scientific evidence. The Service utilized knowledge gained in the last 5 years, as well as that gained well beyond the past five years. The standard by which the Service must make a determination is not ''which mitigation measures and monitoring requirements are absolutely necessary,'' as stated by the commenter. As set forth in 50 CFR 18.27(d), in evaluating an authorization request, if the Service finds that mitigating measures would render the impact of the specified activity negligible when it would not otherwise satisfy that requirement, the Service may make a finding of negligible impact subject to those mitigation measures. As new information is developed, through monitoring, reporting, or research, the regulations may be modified, in whole or part, after notice and opportunity for public review.

Comment 43: The Service should consider the use of passive acoustic monitoring (PAM) to clear the exclusion zones associated with seismic operations when it is not possible to do so visually.

Response: The Service considered the availability and feasibility (economic and technological) of equipment, methods, and manner of conducting proposed activities or other means of effecting the least practicable adverse impact upon the affected species or stocks, their habitat, and on their availability for subsistence uses. Passive acoustic monitoring (PAM) has been evaluated by Industry for use in the Chukchi Sea. It is a potentially useful technology, but has not yet been widely adopted in the Chukchi Sea due to technical limitations. Therefore, while the Service encourages the continuing development and testing of technologies such as PAM, we have not required its use in these regulations.

Comment 44: The Service should reconsider the requirement to monitor for aggregations of walruses within 160 dB isopleth because it requires very large observation zones that are both highly questionable given a science-based risk assessment and impractical to implement with confidence.

Response: We agree; however, the intent of this mitigation measure is to detect animals before they venture into the 180 dB isopleth where temporary or permanent threshold shifts may occur. By monitoring as much of the 160 dB isopleth as possible, MMOs on seismic vessels will detect the majority of animals before they are potentially injured and Industry will have adequate time to implement mitigation measures so that potential injury is avoided.

Comment 45: The proposed rule uses the sound pressure level of 160 dB re 1 μPa (RMS) as a threshold for behavioral, sub-lethal take of Pacific walruses. This approach does not reflect the best available science, and the choice of threshold is not sufficiently conservative.

Response: There are no sound pressure level studies specific to walruses of which we are aware. However, data are available for three arctic seal species, and our use of thresholds is consistent with that data.

Comment 46: The Service cannot rationally defend its conclusion that proposed seismic surveys will harm no more than small numbers of marine mammals and will have no more than negligible impacts on those species or stocks. The Service should consider an alternative that examines whether takes occur at sound thresholds lower than 160 dB.

Response: The 160 dB threshold is the only acoustic threshold that has been described for pinnipeds, predominantly for seals, and our use of these thresholds for walruses is consistent with that data. Currently, there are no data available to analyze a different lower limit. Damage to hearing has not been demonstrated at 160 dB, and the 160 dB isopleth defines the area in which operators must begin to take measures (ramp down, shut down) to avoid hearing loss in walruses (which presumably occurs at 180 dB) similar to other pinnipeds.

Comment 47: Pre-booming requirements for fuel transfer during seismic survey operations is not possible and should be removed as a requirement.

Response: The Service acknowledges that pre-booming for moving vessels, such as during a seismic survey operation, is not possible. Pre-booming

for fuel transfers during seismic survey operations is not a specific requirement in this rule. It is discussed in the **SUPPLEMENTARY INFORMATION** section of the proposed rule in the context of BOEM Lease Sale 193 Lease Stipulations. This is a stipulation from a different Federal agency that could potentially benefit our trust species by minimizing impacts in the environment. This text has been revised in this final rule to indicate that operators must operate in full compliance with a BOEM/BSEE approved Oil Spill Prevention and Response Plan. Proposed operations in sensitive habitat areas will be reviewed by the Service on a case-by-case basis and may result in the prescription of additional mitigation measures (such as pre-booming of vessels during fuel transfers) through the LOA process.

Comment 48: The Service needs to provide a template in regards to the raw data requirement for collecting and transmitting marine mammal data.

Response: The Service worked with Industry to create such a template, and this template is already in use by several operators and their consultants in the Chukchi Sea. The Service provides the template when issuing an LOA, and we believe the current template is sufficient for current data collections. If new types of data are collected, the Service will work with Industry to develop an appropriate updated template.

Comment 49: The Service should more precisely (spatially and temporally) tailor coastal exclusion zones to protect subsistence activities where and when they occur.

Response: The Service disagrees. It is not appropriate to restrict exclusion zones temporally because hunting could occur at any time of the year. It is not appropriate to spatially restrict exclusions zones because the Service considered the best available information concerning walrus and polar bear hunting practices along the western coast of Alaska adjacent to the Chukchi Sea, including discussions with hunting boat captains and other hunters over the years in the field and information collected through the Service Marking Tagging and Reporting Program (harvest monitoring) in defining the 40-mile radius around subsistence hunting communities. Additional studies will be considered when they become available. Based on the information at hand, the Service believes the 40-mile radius is an accurate depiction of the open-water season area used by a majority of walrus and polar bear hunters. A minority of hunters have reported hunting trips that include a 60- to 70-mile one-way distance from their village.

Comment 50: The Service should develop and consider an alternative approach with seismic survey exclusion zones based on the levels at which received sound begins to disrupt walrus and polar bear behavior patterns, as opposed to actually causing physiological injury.

Response: The Service is not in a position to develop an alternative approach with exclusion zones based on the levels at which received sound begins to disrupt walrus and polar bear behavior patterns. This would be very hard, if not impossible, to determine for animals in the wild. Testing of captive animals in a zoo is not relevant for behavioral change, as aquaria conditions are unique and confined. The Service assumes that the majority of walruses exposed to anthropogenic sounds will leave the area. In fact, we specify seismic ramp-up procedures to clear an area of animals before potential injury-producing surveys can occur. Research suggests that behavioral responses can be observed in seals exposed to 160 dB levels. However, not all animals are disturbed at this level. In addition, these behavioral responses are generally not biologically significant in terms of altering the survival or reproductive potential of the individual or the population.

4. Takings

Comment 51: It is not clear what the Service relied on to arrive at the number ''12'' as a trigger for special regulatory protections for walruses, and the Service has not indicated what potential biologically significant activities might be indicated by 12 individual walruses.

Response: The number 12 is used to define a group of walruses in the water that are assumed to be foraging or migrating. The number 12 was originally adopted in 2006, because it was consistent with NMFS' incidental harassment authorizations (IHAs) for foraging whales, which was the best information available at that time. However, NMFS no longer uses that standard. As an alternative, the Service reviewed the data on Industry encounters with walruses during 1989, 1990, and 2006–2012, and calculated the average reported group size of walruses. Group sizes ranged from 7 to 16 walruses, with a mean of 12 (16 in 1989, 13 in 1990, and 7 from 2006–2012). Furthermore, observations of 12 or more walruses at the surface of the water likely represent a larger number of walruses in the immediate area that are not observed (possibly up to 70 individuals or more).

Comment 52: The best available data and information demonstrate that all (not ''most'') of the anticipated walrus takes will be limited to minor behavioral modifications and short-term changes in behavior, or Level B harassment.

Response: We do not agree that it would be accurate to state that ''the best available data and information demonstrate that all (not ''most'') of the anticipated walrus takes will be limited to minor behavioral modifications and short-term changes in behavior.'' The Service believes that there is a small chance for some harassment to occur beyond Level B. We note, however, that the only type of take we anticipate to occur under these regulations is Level B harassment, which is defined as any act of pursuit, torment, or annoyance which has the potential to disturb a marine mammal or stock by causing disruption of behavioral patterns, including migration, breathing, nursing, breeding, feeding, or sheltering.

Comment 53: The Service should clarify whether protecting polar bears or walruses through intentional hazing will be authorized under this rule during various activities, such as ice management.

Response: The proposed rule clearly states that intentional take, also called directed take or deterrence, is not covered (50 CFR 18.116 and 18.117) under this rule. The discussion in the preamble relates to how a situation with walruses on ice in the vicinity of a drill rig may be managed under various authorities of the MMPA, where activities deemed necessary to minimize potential injury to the animals could be authorized under separate sections of the MMPA.

Comment 54: It is unclear whether the proposed rule does or does not authorize management of ice floes occupied by walruses or polar bears.

Response: The proposed rule would authorize the management of ice floes occupied by walruses and polar bears. Ice floes that have the potential to move into the path of the exploration program will be monitored by the Industry. If any walruses are on a floe that might need to be deflected or broken apart they will be monitored in order to plan the appropriate time to actively manage the floe. During this time period, incidental take of the animals may occur. In the event that walruses remain on the ice floe(s) in question, the Service will work cooperatively with Industry to make a determination that the floe(s) containing walruses need to be deflected or broken up in order to minimize damage to the drill rig or moorings. At that time, the Service will make a determination for

Industry to actively (intentionally) move the walruses off the ice in a safe manner to minimize disturbance and limit impacts to the walruses so that the floe can be actively managed by deflecting it or breaking it apart. This activity, the intentional take of walruses, will be addressed under a separate provision of the MMPA. Polar bears could also be intentionally moved in the same manner if the Service made the determination that it was in the best interest of the animal.

The regulations also state that this will be dealt with in real time on a case-by-case basis. For example, if a floe has to be managed and it contains walruses, the operator will call Service personnel before taking any action. Once the Service is apprised of the particulars of the situation, we will make recommendations about how to proceed, maintaining direct, real-time communication with the operator as long as necessary.

Comment 55: The Service erroneously concludes that seismic surveys are unlikely to cause serious impacts to polar bears because they rarely dive below the surface. However, bears can specialize in aquatic stalks of seals at which time they may be impacted.

Response: The Service disagrees. Polar bears do stalk seals through the water when seals are resting or basking on floes of sea ice. Polar bears may swim for a short period of time under water while stalking and may encounter underwater noise created by oil and gas activities. However, there is no indication that the mere presence of anthropogenic noise in the underwater environment will affect the success of a hunt by a polar bear. Ultimately the bear is approaching a seal out of water. Although the underwater hearing characteristics of polar bears are poorly known, the Service has no reason to believe that bears are more prone to acoustical injury than other marine mammals.

Furthermore, polar bears, seals, ice, and excessive anthropogenic noise have to be in the same place at the same time for a situation such as the one described by the commenter to occur. There is very limited ice during the open-water period, when oil and gas activity occurs in the region, and polar bears are rarely encountered in the water during this time period. Furthermore, there is a low probability that seals will be disturbed from resting or basking due to anthropogenic noise, as there is limited ice for seals to bask on at this time, and as most oil and gas operations do not operate in or near ice during the open-water period. Seismic surveys, for example, avoid sea ice because of the complexity of navigating through ice and the likelihood that the ice will interfere with the towed seismic array. In the absence of specific data on polar bears, the Service has adopted monitoring and mitigation standards established for other marine mammal species. Additionally, monitoring and reporting conditions specified in this rule require oil and gas activities to maintain certain minimum distances from observed polar bears and Pacific walruses. The Service believes these mitigation and monitoring measures will ensure that the negligible impact requirement of the MMPA is met.

Comment 56: The Service has not analyzed impacts or estimated take to either of the two distinct walrus population stocks. Further, the Service has not even acknowledged their separate status.

Response: Currently, the Society for Marine Mammalogy recognizes only one stock/population of Pacific walruses. This conclusion is based on both genetic and morphological analyses of the groups that winter in different regions and the resulting little differentiation with the group that winters in the Laptev Sea that was previously considered a separate population.

Comment 57: The Service fails to find that only a small number of takes will occur and has likely significantly underestimated the number of takes that will occur.

Response: The Service is confident that only small numbers of walruses and polar bears will be taken by the proposed activities. Although a precise numerical estimate of the number of Pacific walruses and polar bears that might be taken incidental to specified activities currently could not be practically obtained, the Service deduced that only small numbers of Pacific walruses and polar bears, relative to their populations, have the potential to be impacted by the proposed Industry activities described in these regulations. This conclusion was based on the best available scientific information regarding the habitat use patterns of walruses and polar bears, and the distribution of walruses and bears relative to where Industry activities are expected to occur. In addition to our response, we have further clarified our explanation of small numbers in this rule (see Summary of Take Estimates for Pacific Walruses and Polar Bears).

Furthermore, the Service's analysis of oil and gas activities for this rulemaking encapsulates all of the known oil and gas Industry's activities, as outlined in the petition submitted by AOGA, that will occur in the geographic region during the 5-year regulatory period. If any additional activities are proposed that were not included in the Industry petition or otherwise known at this time, the Service will evaluate the potential impacts associated with those projects to determine whether a given project lies within the scope of the analysis for these regulations. The Service has analyzed oil and gas operations and has taken into account risk factors to polar bears and walruses, such as potential habitat loss due to climate change, hunting, disease, oil spills, contaminants, and effects on prey species within the geographic region. The Service's analysis for this rulemaking also considers cumulative effects of all oil and gas activities in the area over time. Cumulative impacts of oil and gas activities are assessed, in part, through the information we gain in monitoring reports, which are required for each operator under the authorizations. ITRs have been in place in the Arctic oil and gas fields for the past 22 years. Information from these reports provides a history of past effects on walruses and polar bears from interactions with oil and gas activities. The Service used information on previous levels of impacts to evaluate future impacts from existing and proposed Industry activities and facilities. In addition, our cumulative effects assessment includes research publications and data, traditional knowledge of polar bear and walrus habitat use, anecdotal observations, and professional judgment.

Monitoring results indicate minor, short-term to no impact on polar bears or Pacific walruses from oil and gas activities. We evaluated the sum total of both subtle and acute impacts likely to occur from industrial activity and, using this information, we determined that all direct and indirect effects, including cumulative effects, of industrial activities will not adversely affect the species through effects on annual rates of recruitment or survival. Based on past monitoring reports, the level of interaction between Industry and polar bears and Pacific walruses is minimal. Additional information, such as subsistence harvest levels and incidental observations of polar bears near shore, provide evidence that these populations have not been adversely affected. For the next 5 years, we anticipate the level of oil and gas Industry interactions with polar bears and Pacific walruses will be similar to interactions in previous years.

Comment 58: The Service lacks sufficient scientific evidence to authorize takes of marine mammals, and where the Service has not complied

with section 1373 of the MMPA, the Service may not authorize takes.

Response: The Service disagrees. The Service believes that it is in full compliance with the MMPA in this rule. Using the best available scientific information, the Service analyzed marine mammal data from our agency, Industry, and other outside sources to make a determination that the described activities in the proposed rule will affect only small numbers of polar bears and walruses, and have no more than a negligible impact on the stock.

Comment 59: The Service has underestimated the number of takes that will occur due to aquatic anthropogenic sound, because it only considered takes in the form of actual hearing injuries (e.g., hearing threshold shifts), and failed to account for takes in the form of behavioral disturbance.

Response: The Service did consider behavioral disturbances when analyzing the level of take likely to occur. We believe that the behavioral responses observed during previous Industry activities, which were analyzed for take, were only non-injurious (Level B harassment) takes. Further, we do not anticipate any actual injury to animals (Level A harassment).

5. Analysis

Comment 60: The Service's conclusions are not based on the best available science and are therefore questionable.

Response: We disagree. The Service put significant effort into ensuring that it was using the best available scientific information before making affirmative determinations that the incidental take under this rule will affect only small numbers of polar bears and walruses, have no more than a negligible impact on the stocks, and will not have an unmitigable adverse effect on the availability of those species for subsistence uses. In addition, the mitigation measures required under the rule further reduce the potential for negative impacts on population or subsistence. Although the Service is actively engaged in ongoing studies on climate change, polar bears, and walruses in the Arctic, the Service is required to make a determination on ''best available'' science and is not required to wait until additional science is publically available.

Comment 61: The Service should provide its best estimate of the numbers and types of walrus takes that could result from the proposed exploration activities each year.

Response: This cannot be accomplished with much reliability due to the highly variable environmental conditions (e.g., currents, winds, sea ice dynamics, walrus migration patterns and distribution, Industry activity levels and locations, etc.) that occur among and within years. However, numbers of animals encountered during Industry activities in previous years does provide an indication of the type and numbers of takes that may be expected, which are presented in Table 3 in the Analysis of Impacts of the Oil and Gas Industry on Pacific Walruses and Polar Bears in the Chukchi Sea section of this final rule.

Comment 62: The proposed regulations do not ensure that only small numbers of marine mammals will be taken.

Response: We disagree. Authorized activities are limited by the operating restrictions set forth in this rule and by conditions stipulated in LOAs. Section 101(a)(5)(A) of the MMPA provides for the incidental, but not intentional, take of small numbers of marine mammals, provided that the total take will have no more than a negligible impact on the populations and will not affect the availability of the species for subsistence users. The Service believes that potential impacts to walruses, polar bears, and the subsistence use of these resources are greatly reduced through the operating restrictions, monitoring programs, and adaptive management responses set forth in this rule.

Based on observations from 2006–2010 (Table 3 in the Analysis of Impacts of the Oil and Gas Industry on Pacific Walruses and Polar Bears in the Chukchi Sea section of this final rule), we can conclude that less than 2 percent of a population of over 129,000 walruses will be encountered during Industry activities annually. In addition, less than 34 percent of those encounters will result in a reaction by walruses, and few if any of these reactions are biologically significant in terms of survival and reproduction at the individual or population level. To help ensure that the small numbers standard is met, the Service monitors the take of walruses and polar bears weekly as operations are occurring and will alert Industry operators when takes may begin to exceed small numbers.

Comment 63: The Service has not estimated existing levels of walruses or polar bears.

Response: The Service has analyzed population estimates for walruses and polar bears. However, there is no recent, reliable census information for either walruses or polar bears in the Chukchi Sea region. Furthermore, the distribution and abundance of walruses and polar bears in the specified geographical region considered in these regulations is expected to fluctuate dramatically on a seasonal and annual basis in response to dynamic ice conditions. Consequently, it is not practical to provide *a priori* numerical estimates of the number of walruses or polar bears that might occur within the specified geographical region in any given year, or to quantify, with any statistical reliability, the number of animals that could potentially be exposed to industrial noise during this time frame. Nevertheless, based on other factors, such as Industry monitoring reports and agency monitoring programs (ASAMM), we are able to deduce with a high degree of confidence that only small numbers of Pacific walruses and polar bears are likely to be impacted by the proposed activities based on observations from 2006–2012. The factors considered in this finding are detailed in the Summary of Take Estimates for Pacific Walruses and Polar Bears.

Comment 64: The Service should work independently or jointly with the National Marine Fisheries Service and Marine Mammal Commission to develop a policy that sets forth the criteria for determining what constitutes ''small numbers'' and ''negligible impact'' for the purposes of authorizing incidental takes of marine mammals.

Response: In finalizing this rule, the Service has considered what constitutes small numbers as well as negligible impact for the purposes of authorizing the incidental take of marine mammals. We recognize the important contributions NMFS and the Marine Mammal Commission have made in our agencies' requirements to implement the MMPA, and we are always willing to discuss joint efforts where we hold a shared interest in the conservation of species and the environment.

Comment 65: The Service fails to explain how 125 polar bears is a ''small number.''

Response: The Service's determination that 125 polar bears (25 bears annually) constitutes a small number within the meaning of the MMPA is based on the fact the 125 polar bears is small relative to the total abundance of the Chukchi-Bering Sea and Southern Beaufort Sea polar bear populations, which consists of approximately 3,500 total bears collectively.

Comment 66: The Service improperly conflates ''small numbers'' with ''negligible impacts.''

Response: We disagree. The Service's determination that the takings are limited to small numbers was analyzed independently of its determination that those takings will have a negligible impact. The Service's analysis of

negligible impact was based on the distribution and number of the species during proposed activities, its biological characteristics, the nature of the proposed activities, the potential effects, documented impacts, mitigation measures that will be implemented, as well as other data provided by monitoring programs in the Chukchi Sea.

Comment 67: The Service has failed to prescribe methods and means of affecting the ''least practicable adverse impact'' on the species or stock and its habitat. It relies on mitigation measures that have been proven to be ineffective while declining to require more appropriate mitigation.

Response: The Service disagrees. However, the Service welcomes any new evidence or specific information on how our proposed mitigation, monitoring, and reporting measures have proven to be ineffective or how they may be improved. The Service will consider such information when provided.

Comment 68: The proposed rule fails to consider that seismic survey vessels use the lowest practicable sound source levels, minimize horizontal propagation of the sound signal from acoustic arrays, and minimize the density of seismic survey track lines.

Response: The Service believes that the monitoring and mitigation measures set forth in these regulations are necessary and appropriate to limit disturbance and Industry impacts on polar bears and Pacific walruses.

Comment 69: The proposed rule fails to consider a requirement that all vessels undergo measurement for their underwater noise output per American National Standards Institute/Acoustical Society of America standards, that all vessels undergo regular maintenance to minimize propeller cavitation, and/or that all new vessels be required to employ the best ship quieting designs and technologies available for their class of ship.

Response: The Service believes that the monitoring and mitigation measures set forth in these regulations are necessary and appropriate to limit disturbance and Industry impacts on polar bears and Pacific walruses. However, many of the practices recommended by the commenter are utilized by various Industry operators and some are required by other agencies, regulations, and permits.

Comment 70: The proposed rule fails to consider a speed limit (e.g., 10 knots) placed on all vessels transiting to and from a work site, with consideration for additional limits on vessel speed when transiting through important habitat areas.

Response: The Service does not consider a universal speed limit (e.g., 10 knots) on all vessels to be a practicable or effective mitigation measure. However, MMO observations of polar bears or walruses can trigger speed reductions and other mitigation responses from vessels.

Comment 71: The proposed rule fails to consider additional best practices for monitoring and maintaining safety zones around active airgun arrays as set forth in Weir and Dolman (2007) and Parsons *et al.* (2009).

Response: While the Service does not adopt all the recommendations in the references cited by the commenter, we do adopt most of them. The mitigation, monitoring and reporting measures included in this rule are consistent with the best practices ''for monitoring and maintaining safety zones around active airgun arrays.'' In fact, the measures proposed for seismic survey operations in this rule, and contained in past ITRs, exceed the requirements of many jurisdictions elsewhere in the world. Taken in conjunction with other regulations and permits by other agencies, the practices for mitigation, monitoring, and reporting for seismic survey activities in the Chukchi Sea will limit disturbances to polar bears and walruses.

Comment 72: The proposed rule fails to consider a deferral on exploration drilling until the concerns detailed by the U.S. Oil Spill Commission are adequately addressed.

Response: The Service does not have the authority under the MMPA to authorize or ''permit'' the actual activities associated with oil and gas exploration, e.g., exploratory drilling. Rather, these regulations only authorize the nonlethal, incidental, unintentional take of small numbers of polar bears and walruses associated with those activities based on standards set forth in the MMPA.

Comment 73: The MMPA explicitly requires that the prescribed regulations include other ''means of effecting the least practicable adverse impact'' on a species, stock, or habitat. Regulations must explain why measures that will reduce the impact on a species were not chosen (i.e., why they were not ''practicable'').

Response: Although the MMPA does provide a mechanism for the Secretary to prescribe regulations that include ''other means of affecting the least practicable adverse impact'' on a species, stock, and its habitat, the regulations do not require the Secretary to provide an explanation for measures that were determined to be impracticable. In fact, all measures that are practicable and will provide a means to minimize adverse impacts to the species as a result of the proposed activities should be included in the prescribed regulations. The Service believes it has included a full suite of means to minimize impacts to Pacific walruses and polar bears that could result from oil and gas exploration activities. As mentioned above, the regulations describe which mitigation measures are always required for certain activities and which can be selectively used to mitigate Level B harassment of polar bears and walruses. The Service adaptively prescribes these additional mitigation and monitoring requirements through the LOA process on a case-by-case basis because certain mitigation measures may not be appropriate in every situation. This adaptability allows us to implement all ''means of affecting the least practicable impact.''

Comment 74: The Service should specify reduced vessel speeds of 9 knots or less when (1) weather conditions or darkness reduce visibility and (2) within 805 m (0.5 mi) of aggregations of 12 or more walruses.

Response: We disagree. We recognize that MMO data indicate that speeds are generally reduced when walruses within 0.5 mi are encountered, sometimes to 4 or 5 knots. However, we note that ship safety is ultimately not determined by the Service. For example, vessels towing barges have less ability to reduce speeds and maintain control of the tow. Therefore, while a general requirement of reduced speed is appropriate such that Pacific walruses or polar bears are not disturbed, we believe that the actual navigation of the vessels should be based on prevailing conditions and the vessel operators.

6. Other Regulatory Issues and Agreements

Comment 75: One commenter supported the timely issuance of 5-year ITRs authorizing nonlethal, incidental, unintentional take.

Response: We agree. The Service views ITRs as an important conservation management tool for Pacific walruses and polar bears.

Comment 76: The ITRs and draft EA do not clearly explain in the environmental consequences analyses when a seismic exposure has a behavioral effect, whether this rises to be a countable take, and finally whether any of this is biologically significant at either an individual or population level.

Response: The ensonification zones are a proxy for the amount of sound or seismic disturbance that will be

considered to rise to the level of biologically significant disturbance, i.e., Level B take. All of this was considered in our small numbers and negligible impact analysis as explained in the **SUPPLEMENTARY INFORMATION** section of the proposed rule and this final rule.

Comment 77: For seismic operations, the requirements associated with monitoring and shutdown for aggregation of walruses is questionable based upon the documented behavior of this species in the 2008–2013 monitoring data.

Response: We disagree. The Service applies mitigation measures in a conservative manner, as we are tasked with trying to minimize disturbance and impacts to animals observed and unobserved in the water. The data indicate that for the most part, these measures are effective, as the majority of observable walruses do not respond to Industry activities.

Comment 78: One commenter encouraged the Service to work with the Council on Environmental Quality (CEQ) to ''energize and return to the MMPA's original policy ideals.''

Response: The Service and CEQ work together to ensure the regulatory framework reflects the meaning and intent of the laws passed by Congress.

Comment 79: The Service should facilitate the development of conflict avoidance agreements to ensure consensus-based agreement between potentially affected communities and oil and gas operators regarding measures to avoid unmitigable adverse impacts on polar bears and walruses taken for subsistence purposes.

Response: As stated in 50 CFR 18.114, the Service relies on a POC to mitigate potential conflicts between the proposed activity and potentially affected communities where subsistence hunting may be impacted, rather than a conflict avoidance agreement, generally used by NMFS to mitigate Industry impacts to their trust species. The POC is developed by Industry and is a document that involves Industry and the affected subsistence communities. It is included as a section of the incidental take request packet submitted by Industry to the Service. Within that context, the POC process requires presentation of project specific information, such as operation plans, to the communities to identify any specific concerns that need to be addressed. It is impossible to develop a POC until the nature of specific projects is identified and the concerns of the affected community are heard. Coordination with the affected subsistence communities and development of the POC is the responsibility of Industry; however, the Service offers guidance during the process, if necessary. The requirements and process for the POC, including the Services' right to review and reject the POC if it does not provide adequate safeguards to ensure that marine mammals will remain available for subsistence use, are described in the **SUPPLEMENTARY INFORMATION** section of this rule and reiterated in the regulations.

Comment 80: The proposed regulations do not comply with the MMPA.

Response: We disagree. Section 101(a)(5)(A) of the MMPA provides for the incidental, but not intentional, take of small numbers of marine mammals, provided that the total take will have a negligible impact on the population and will not affect the availability of the species for subsistence users. In accordance with the regulations, Industry activities will be subject to the operating restrictions, monitoring requirements, and adaptive management responses set forth in this rule and by conditions stipulated in LOAs, which the Service believes will greatly reduce potential impacts to walruses, polar bears, and the subsistence use of these resources. Accordingly, the Service believes that the take of walruses and polar bears incidental to Industry activities satisfies the requirements of section 101(a)(5)(A) of the MMPA.

Comment 81: One commenter urged the Service to take a precautionary, science-based, approach to the petitioners' request, and specifically requested that, if the regulations are issued, the Service include strict monitoring and oversight requirements to ensure that the MMPA's standards are met and transparently documented to the public.

Response: We agree. The Service is committed to conserving and managing Pacific walruses and polar bears. We believe these regulations include the necessary mitigation and monitoring requirements to meet all aspects of the MMPA, and the Service is committed to being a transparent and open government agency.

Comment 82: One commenter encouraged the Service to complete an intra-agency consultation on polar bears.

Response: We agree and completed intra-Service consultation under the ESA on the polar bear and conference on the Pacific walruses prior to issuing these final regulations.

Comment 83: The Service should advise AOGA of the desirability of initiating a conference for the walrus to help fulfill its obligations under the Endangered Species Act for the 5-year period of these final regulations.

Response: The Service agrees with this comment. Since the notice announcing the conclusion of the status review of the Pacific walrus was published (76 FR 7634; February 10, 2011) and the Pacific walrus was added to the list of candidate species under the ESA, we have advised applicants for LOAs, when applicable and appropriate, of their option to initiate a conference with the Service regarding Pacific walruses.

Comment 84: The proposed rule and draft EA should be updated to reflect recent legal developments regarding polar bear critical habitat.

Response: We agree. We added text to this rule to acknowledge that the final rule designating critical habitat for the polar bear (75 FR 76086; December 7, 2010) was recently vacated in Federal district court.

Comment 85: The Service should consider restricting activities in specific polar bear critical habitat areas.

Response: Because the final rule designating critical habitat for the polar bear (75 FR 76086; December 7, 2010) was recently vacated in Federal district court, critical habitat is no longer designated for the polar bear.

Comment 86: The proposed rule does not explain that certain ringed and bearded seal subspecies have recently been listed as ''threatened'' under the ESA. The final rule should reflect this change in status.

Response: Ringed and bearded seals are not managed by the Service, and we do not issue take authorization for those species. However, we are aware of the recent listing of these species, and text has been added to this rule to explain the recent determination.

Comment 87: The proposed regulations appear to be inconsistent and contravene both the 1973 Agreement on Conservation of Polar Bears and the 2000 Bilateral Agreement for the Conservation and Management of the Polar Bear between the United States and the Russian Federation, because authorizing Industry activities violates the mandates of the these agreements to protect important polar bear habitat.

Response: We disagree. The regulations are consistent with the mandates of both the 1973 and 2000 Agreements as set forth in Article II of each of the agreements. Those provisions require that the United States take actions to protect the ecosystem of which polar bears are a part, giving ''special attention to habitat components such as denning and feeding sites and migration patterns,'' and to manage

polar bear populations in accordance with ''sound conservation practices'' based on the best available scientific data.

This rule is consistent with the Service's treaty obligations because it incorporates mitigation measures that ensure the protection of polar bear habitat. The anticipated LOAs for industrial activities will be conditioned to include area or seasonal timing limitations or prohibitions that will adequately protect polar bear habitat. For example, 1-mile avoidance buffers will be placed around known or observed dens, which will stop or limit Industry activity until the bear naturally leaves the den.

In addition to the protections provided for known or observed dens, we have incorporated considerations in the ITRs for Industry to use or assist in use of Forward Looking Infra-Red (FLIR) thermal imagery to detect the heat signatures of polar bear dens. By conducting FLIR surveys prior to initiating activities to identify potential polar bear dens, disturbance of even unknown denning females is limited. Industry has also used digital elevation models and aerial imagery to identify habitats suitable for denning.

Other important protections in LOAs issued in accordance with these final ITRs include the development of polar bear-human interaction plans to minimize potential for encounters and to mitigate adverse effects should an encounter occur. These plans protect and enhance the safety of polar bears using habitats within the area of industrial activity. Finally, as outlined in our regulations at 50 CFR 18.27(f)(5), LOAs may be withdrawn or suspended, if noncompliance of the prescribed regulations occurs.

Comment 88: The Service must prepare a full environmental impact statement (EIS) to meet the requirements of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 et seq.).

Response: The regulations implementing NEPA at 40 CFR 1501.4(b) provide that, in determining whether to prepare an EIS, a Federal agency may prepare an EA and, based on the EA document, make a determination whether to prepare an EIS. The Department of the Interior's policy and procedures for compliance with NEPA (69 FR 10866; March 8, 2004) further affirm that the purpose of an EA is to allow the responsible official to determine whether to prepare an EIS or a ''Finding of No Significant Impact'' (FONSI). The Service analyzed the proposed activity, i.e., issuance of implementing regulations, in accordance with the criteria of NEPA, and made a determination that it does not constitute a major Federal action significantly affecting the quality of the human environment. It should be noted that the Service does not authorize the actual Industry activities, as those activities are authorized by other State and Federal agencies. The Service merely authorizes the take of polar bears and walruses incidental to those activities. We note that these regulations provide the Service with a means of interacting with Industry through the mitigation and monitoring programs of individual projects to ensure that the impacts to polar bears and Pacific walruses are minimized. We have determined that the regulations will result in the nonlethal, incidental take of only small numbers of polar bears and Pacific walruses, will have only a negligible impact on the stocks, and will not have an unmitigable adverse impact on subsistence users. As a result, we determined the regulations will not significantly affect the quality of the human environment and, therefore, a FONSI is appropriate. Accordingly, an EIS is not required under NEPA.

7. Additional Suggested Requirements

Comment 89: The proposed rule fails to include any measures to require, incentivize, or test the use of new technologies in the Arctic.

Response: The Service does not have the authority under the MMPA nor the technical expertise to require, incentivize, or test the use of new technologies in the manner the commenter suggests. The Service does work with various partners to recommend the use of new technologies, such as FLIR imagery to detect polar bears on the ice or their dens or the use of UASs to conduct offshore marine mammal monitoring. The MMPA does not provide specific mechanisms for the Service to accomplish this goal, but we will work with those seeking LOAs during the regulatory process to capitalize on existing and emerging technologies. Clarifying text has been added to this rule.

Comment 90: The proposed rule appears to be shifting from monitoring of existing operations to an extensive research program.

Response: As stated earlier, the type of monitoring activities required by these ITRs has been clarified through additional explanation. All such monitoring and reporting requirements provide us with additional information upon which to assess the efficacy of these regulations, our associated LOAs, and ultimately any impacts to polar bears and Pacific walruses.

While one basic purpose of monitoring polar bears and walruses in association with Industry is to establish baseline information on habitat use and encounters and to detect any unforeseen effects of Industry activities, broad-based, long-term monitoring programs are useful to refine our understanding of the impacts of oil and gas activities on polar bears, walruses, and their habitat over time in the Chukchi Sea. However, a broad-based population monitoring plan will need to incorporate research elements as well. When making our findings, the Service uses the best and most current information regarding polar bears and walruses. The integration of, and improvement in, research and monitoring programs are useful to assess potential effects to rates of recruitment and survival and to the population parameters linked to assessing population-level impacts from oil and gas development. Our description in these regulations is an extension of this type of thinking.

As expressed in previous regulations, where information gaps are identified, the Service will work to address them. Monitoring and reporting results specified through the LOA process during authorized exploration activities are expected to contribute information concerning walrus and polar bear distributions and habitat use patterns within the Chukchi Sea Lease sale area. The Service has analyzed the results of a joint U.S./Russia walrus population survey carried out in 2006, and is sponsoring research investigating the distribution and habitat use patterns of Pacific walruses in the Chukchi Sea. This information will be incorporated into the decision-making process.

Monitoring provisions associated with these types of regulations were never intended as the sole means to determine whether the activities will have a negligible effect on polar bear or walrus populations. There is nothing in the MMPA that indicates that Industry is wholly responsible for conducting general population research, but participation may be requested to help answer biological questions. Thus, we have not required Industry to conduct such population research and instead require monitoring of the observed effect of the activity on polar bear and walrus. We are constantly accumulating information, such as reviewing elements of existing and future research and monitoring plans that will improve our ability to detect and measure changes in the polar bear and walrus populations. We further acknowledge that additional or complimentary research, studies, and information, collected in a timely fashion, are useful to better evaluate the

effects of oil and gas activities on polar bears and walruses in the future.

Required Determinations

National Environmental Policy Act (NEPA) Considerations

We have prepared an environmental assessment (EA) in conjunction with this rulemaking, and have determined that this rulemaking is not a major Federal action significantly affecting the quality of the human environment within the meaning of Section 102(2)(C) of the NEPA of 1969. For a copy of the EA, go to *http://www.regulations.gov* and search for Docket No. FWS–R7–ES–2012–0043 or contact the individual identified above in the section **FOR FURTHER INFORMATION CONTACT.**

Endangered Species Act (ESA)

On May 15, 2008, the Service listed the polar bear as a threatened species under the ESA (73 FR 28212), and on December 7, 2010 (75 FR 76086), the Service designated critical habitat for polar bear populations in the United States, effective January 6, 2011. On January 13, 2013, the U.S. District Court for the District of Alaska issued an order that vacated and remanded to the Service the final rule designating critical habitat for the polar bear. Sections 7(a)(1) and 7(a)(2) of the ESA (16 U.S.C. 1536(a)(1) and (2)) direct the Service to review its programs and to utilize such programs in the furtherance of the purposes of the ESA and to ensure that an action is not likely to jeopardize the continued existence of an ESA-listed species or result in the destruction or adverse modification of critical habitat. In addition, the status of walruses rangewide was reviewed for potential listing under the ESA. The listing of walruses was found to be warranted, but precluded due to higher priority listing actions (i.e., walrus is a candidate species) on February 10, 2011 (76 FR 7634). Consistent with our statutory obligations, the Service's Marine Mammal Management Office initiated an intra-Service section 7 consultation regarding the effects of these regulations on the polar bear with the Service's Fairbanks Ecological Services Field Office. Consistent with established agency policy, we also conducted a conference regarding the effects of these regulations on the Pacific walrus and the area set forth in the proposed rule to designate critical habitat for the polar bear (74 FR 56058; October 29, 2009). In a biological opinion issued on May 20, 2013, the Service concluded that the action is not likely to jeopardize the continued existence of any listed or candidate species or destroy or adversely modify designated critical habitat.

Regulatory Planning and Review (Executive Order 12866 and 13563)

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) will review all significant rules. The OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation's regulatory system to promote predictability, to reduce uncertainly, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this rule in a manner consistent with these requirements.

Small Business Regulatory Enforcement Fairness Act

We have determined that this rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. The rule is not likely to result in a major increase in costs or prices for consumers, individual industries, or government agencies or have significant adverse effects on competition, employment, productivity, innovation, or on the ability of U.S. based enterprises to compete with foreign-based enterprises in domestic or export markets.

Regulatory Flexibility Act

We have also determined that this rule will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 601 et seq. Oil companies and their contractors conducting exploration, development, and production activities in Alaska have been identified as the only likely applicants under these regulations. Expenses will be related to, but not necessarily limited to, the development of applications for LOAs, monitoring, recordkeeping, and reporting activities conducted during Industry oil and gas operations, development of polar bear interaction plans, and coordination with Alaska Natives to minimize effects of operations on subsistence hunting. Compliance with the rule is not expected to result in additional costs to Industry that it has not already been subjected to for the previous 7 years. Realistically, these costs are minimal in comparison to those related to actual oil and gas exploration, development, and production operations. The actual costs to Industry to develop the petition for promulgation of regulations and LOA requests probably do not exceed $500,000 per year, which is short of the ''major rule'' threshold that would require preparation of a regulatory impact analysis. Therefore, a Regulatory Flexibility Analysis is not required. In addition, these potential applicants have not been identified as small businesses and, therefore, a Small Entity Compliance Guide is not required. The analysis for this rule is available from the individual identified above in the section **FOR FURTHER INFORMATION CONTACT.**

Takings Implications

This rule does not have takings implications under Executive Order 12630 because it allows the authorization of nonlethal, incidental, but not intentional, take of walruses and polar bears by oil and gas Industry companies and thereby exempts these companies from civil and criminal liability as long as they operate in compliance with the terms of their LOAs. Therefore, a takings implications assessment is not required.

Federalism Effects

This rule does not contain policies with Federalism implications sufficient to warrant preparation of a federalism impact summary statement under Executive Order 13132. The MMPA gives the Service the authority and responsibility to protect walruses and polar bears.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501, et seq.), this rule will not ''significantly or uniquely'' affect small governments. A Small Government Agency Plan is not required. The Service has determined and certifies pursuant to the Unfunded Mandates Reform Act that this rulemaking will not impose a cost of $100 million or more in any given year on local or State governments or private entities. This rule will not produce a Federal mandate of $100 million or greater in any year, i.e., it is not a ''significant regulatory action'' under the Unfunded Mandates Reform Act.

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, Secretarial Order 3225, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with federally recognized Tribes on a Government-to-Government basis. In accordance with Secretarial Order 3225 of January 19, 2001 [Endangered Species Act and Subsistence Uses in Alaska (Supplement to Secretarial Order 3206)], Department of the Interior Memorandum of January 18, 2001 (Alaska Government-to-Government Policy), Department of the Interior Secretarial Order 3317 of December 1, 2011 (Tribal Consultation and Policy), and the Native American Policy of the U.S. Fish and Wildlife Service, June 28, 1994, we acknowledge our responsibilities to work directly with Alaska Natives in developing programs for healthy ecosystems, to seek their full and meaningful participation in evaluating and addressing conservation concerns for listed species, to remain sensitive to Alaska Native culture, and to make information available to Tribes. We have evaluated possible effects on federally recognized Alaska Native tribes. Through the LOA process identified in the regulations, Industry presents a communication process, culminating in a POC, if warranted, with the Native communities most likely to be affected and engages these communities in numerous informational meetings.

To facilitate co-management activities, cooperative agreements have been completed by the Service, the Alaska Nanuuq Commission (ANC), the Eskimo Walrus Commission (EWC), and Qayassiq Walrus Commission (QWC). The cooperative agreements fund a wide variety of management issues, including: Commission co-management operations; biological sampling programs; harvest monitoring; collection of Native knowledge in management; international coordination on management issues; cooperative enforcement of the MMPA; and development of local conservation plans. To help realize mutual management goals, the Service, ANC, QWC, and EWC regularly hold meetings to discuss future expectations and outline a shared vision of co-management.

The Service also has ongoing cooperative relationships with the NSB and the Inupiat-Inuvialuit Game Commission where we work cooperatively to ensure that data collected from harvest and research are used to ensure that polar bears are available for harvest in the future; provide information to co-management partners that allows them to evaluate harvest relative to their management agreements and objectives; and provide information that allows evaluation of the status, trends, and health of polar bear populations.

Through various interactions and partnerships, we have determined that the issuance of these regulations is appropriate. We are open to discussing ways to continually improve our coordination and information exchange, including through the LOA/POC process, as may be requested by Tribes.

Civil Justice Reform

The Departmental Solicitor's Office has determined that these regulations do not unduly burden the judicial system and meet the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988.

Paperwork Reduction Act

This rule contains information collection requirements. We may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. The Information collection requirements included in this rule are approved by the OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). The OMB control number assigned to these information collection requirements is 1018–0070, which expires on January 31, 2014. This control number covers the information collection, recordkeeping, and reporting requirements in 50 CFR part 18, subpart I, which are associated with the development and issuance of specific regulations and LOAs.

Energy Effects

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. This rule provides exceptions from the taking prohibitions of the MMPA for entities engaged in the exploration of oil and gas in the Chukchi Sea and adjacent coast of Alaska. By providing certainty regarding compliance with the MMPA, this rule has a positive effect on Industry and its activities. Although the rule requires Industry to take a number of actions, these actions have been undertaken by Industry for many years as part of similar past regulations. Therefore, this rule is not expected to significantly affect energy supplies, distribution, or use and does not constitute a significant energy action. No Statement of Energy Effects is required.

References

A list of the references cited in this rule is available on the Federal eRulemaking portal (*http://www.regulations.gov*) under Docket No. FWS–R7–ES–2012–0043.

List of Subjects in 50 CFR Part 18

Administrative practice and procedure, Alaska, Imports, Indians, Marine mammals, Oil and gas exploration, Reporting and recordkeeping requirements, Transportation.

Final Regulation Promulgation

For the reasons set forth in the preamble, the Service amends part 18, subchapter B of chapter 1, title 50 of the Code of Federal Regulations as set forth below.

PART 18—MARINE MAMMALS

■ 1. The authority citation of 50 CFR part 18 continues to read as follows:

Authority: 16 U.S.C. 1361 et seq.

■ 2. Add a new subpart I to part 18 to read as follows:

Subpart I—Nonlethal Taking of Pacific Walruses and Polar Bears Incidental to Oil and Gas Exploration Activities in the Chukchi Sea and Adjacent Coast of Alaska

Sec.
18.111 What specified activities does this subpart cover?
18.112 In what specified geographic region does this subpart apply?
18.113 When is this subpart effective?
18.114 How do I obtain a Letter of Authorization?
18.115 What criteria does the Service use to evaluate Letter of Authorization requests?
18.116 What does a Letter of Authorization allow?
18.117 What activities are prohibited?
18.118 What are the mitigation, monitoring, and reporting requirements?
18.119 What are the information collection requirements?

Subpart I—Nonlethal Taking of Pacific Walruses and Polar Bears Incidental to Oil and Gas Exploration Activities in the Chukchi Sea and Adjacent Coast of Alaska

§ 18.111 What specified activities does this subpart cover?

Regulations in this subpart apply to the nonlethal incidental, but not

intentional, take of small numbers of Pacific walruses and polar bears by you (U.S. citizens as defined in § 18.27(c)) while engaged in oil and gas exploration activities in the Chukchi Sea and adjacent western coast of Alaska.

§ 18.112 In what specified geographic region does this subpart apply?

This subpart applies to the specified geographic region defined as the continental shelf of the Arctic Ocean adjacent to western Alaska. This area includes the waters (State of Alaska and Outer Continental Shelf waters) and seabed of the Chukchi Sea, which encompasses all waters north and west of Point Hope (68°20′20″ N, −166°50′40 W, BGN 1947) to the U.S.-Russia Convention Line of 1867, west of a north-south line through Point Barrow (71°23′29″ N, −156°28′30 W, BGN 1944), and up to 200 miles north of Point Barrow. The region also includes the terrestrial coastal land 25 miles inland between the western boundary of the south National Petroleum Reserve—Alaska (NPR–A) near Icy Cape (70°20′00″ N, −148°12′00 W) and the north-south line from Point Barrow. This terrestrial region encompasses a portion of the Northwest and South Planning Areas of the NPR–A. Figure 1 shows the area where this subpart applies.

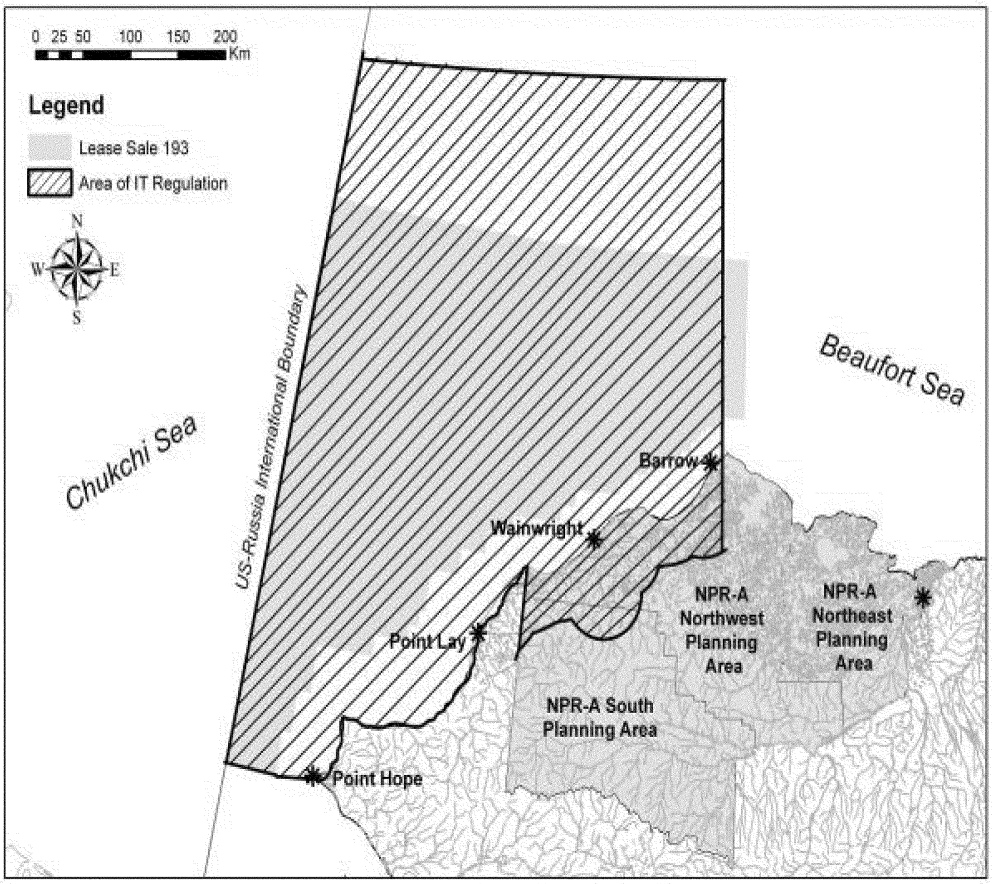

Figure 1: The geographic area of the Chukchi Sea and onshore coastal areas covered by the incidental take regulations.

§ 18.113 When is this subpart effective?

Regulations in this subpart are effective from June 12, 2013 through June 12, 2018 for year-round oil and gas exploration activities.

§ 18.114 How do I obtain a Letter of Authorization?

(a) You must be a U.S. citizen as defined in § 18.27(c).

(b) If you are conducting an oil and gas exploration activity in the specified geographic region described in § 18.112 that may cause the taking of Pacific walruses (walruses) or polar bears and you want nonlethal incidental take authorization under this rule, you must apply for a Letter of Authorization for each exploration activity. You must submit the application for authorization to our Alaska Regional Director (see 50 CFR 2.2 for address) at least 90 days prior to the start of the proposed activity.

(c) Your application for a Letter of Authorization must include the following information:

(1) A description of the activity, the dates and duration of the activity, the specific location, and the estimated area affected by that activity, i.e., a plan of operation.

(2) A site-specific plan to monitor and mitigate the effects of the activity on polar bears and Pacific walruses that may be present during the ongoing activities (i.e., marine mammal monitoring and mitigation plan). Your monitoring program must document the effects to these marine mammals and estimate the actual level and type of

take. The monitoring requirements provided by the Service will vary depending on the activity, the location, and the time of year.

(3) A site-specific polar bear and/or walrus awareness and interaction plan. An interaction plan for each operation will outline the steps the applicant will take to limit animal-human interactions, increase site safety, and minimize impacts to marine mammals.

(4) A record of community consultation or a Plan of Cooperation (POC) to mitigate potential conflicts between the proposed activity and subsistence hunting, when necessary. Applicants must consult with potentially affected subsistence communities along the Chukchi Sea coast (Point Hope, Point Lay, Wainwright, and Barrow) and appropriate subsistence user organizations (the Eskimo Walrus Commission and the Alaska Nanuuq Commission) to discuss the location, timing, and methods of proposed operations and support activities and to identify any potential conflicts with subsistence walrus and polar bear hunting activities in the communities. Applications for Letters of Authorization must include documentation of all consultations with potentially affected user groups and a record of community consultation. Documentation must include a summary of any concerns identified by community members and hunter organizations, and the applicant's responses to identified concerns. Mitigation measures are described in § 18.118.

§ 18.115 What criteria does the Service use to evaluate Letter of Authorization requests?

(a) We will evaluate each request for a Letter of Authorization based on the specific activity and the specific geographic location. We will determine whether the level of activity identified in the request exceeds that analyzed by us in considering the number of animals likely to be taken and evaluating whether there will be a negligible impact on the species or adverse impact on the availability of the species for subsistence uses. If the level of activity is greater, we will reevaluate our findings to determine if those findings continue to be appropriate based on the greater level of activity that you have requested. Depending on the results of the evaluation, we may grant the authorization, add further conditions, or deny the authorization.

(b) In accordance with § 18.27(f)(5), we will make decisions concerning withdrawals of Letters of Authorization, either on an individual or class basis, only after notice and opportunity for public comment.

(c) The requirement for notice and public comment in paragraph (b) of this section will not apply if we determine that an emergency exists that poses a significant risk to the well-being of species or stocks of Pacific walruses or polar bears.

§ 18.116 What does a Letter of Authorization allow?

(a) Your Letter of Authorization may allow the nonlethal incidental, but not intentional, take of walruses and polar bears when you are carrying out one or more of the following activities:

(1) Conducting geological and geophysical surveys and associated activities;

(2) Drilling exploratory wells and associated activities; or

(3) Conducting environmental monitoring activities associated with exploration activities to determine specific impacts of each activity.

(b) Each Letter of Authorization will identify conditions or methods that are specific to the activity and location.

§ 18.117 What activities are prohibited?

(a) Intentional take and lethal incidental take of walruses or polar bears; and

(b) Any take that fails to comply with this part or with the terms and conditions of your Letter of Authorization.

§ 18.118 What are the mitigation, monitoring, and reporting requirements?

(a) *Mitigation.* Holders of a Letter of Authorization must use methods and conduct activities in a manner that minimizes to the greatest extent practicable adverse impacts on walruses and polar bears, their habitat, and on the availability of these marine mammals for subsistence uses. Dynamic management approaches, such as temporal or spatial limitations in response to the presence of marine mammals in a particular place or time or the occurrence of marine mammals engaged in a particularly sensitive activity (such as feeding), must be used to avoid or minimize interactions with polar bears, walruses, and subsistence users of these resources.

(1) *All applicants.* (i) We require holders of Letters of Authorization to cooperate with us and other designated Federal, State, and local agencies to monitor the impacts of oil and gas exploration activities on polar bears and Pacific walruses.

(ii) Holders of Letters of Authorization must designate a qualified individual or individuals to observe, record, and report on the effects of their activities on polar bears and Pacific walruses.

(iii) Holders of Letters of Authorization must have an approved polar bear and/or walrus interaction plan on file with the Service and onsite, and polar bear awareness training will be required of certain personnel. Interaction plans must include:

(A) The type of activity and where and when the activity will occur, i.e., a plan of operation;

(B) A food and waste management plan;

(C) Personnel training materials and procedures;

(D) Site at-risk locations and situations;

(E) Walrus and bear observation and reporting procedures; and

(F) Bear and walrus avoidance and encounter procedures.

(iv) All applicants for a Letter of Authorization must contact affected subsistence communities to discuss potential conflicts caused by location, timing, and methods of proposed operations and submit to us a record of communication that documents these discussions. If appropriate, the applicant for a Letter of Authorization must also submit to us a POC that ensures that activities will not interfere with subsistence hunting and that adverse effects on the availability of polar bear or Pacific walruses are minimized (see § 18.114(c)(4)).

(v) If deemed appropriate by the Service, holders of a Letter of Authorization will be required to hire and train polar bear monitors to alert crew of the presence of polar bears and initiate adaptive mitigation responses.

(2) *Operating conditions for operational and support vessels.* (i) Operational and support vessels must be staffed with dedicated marine mammal observers to alert crew of the presence of walruses and polar bears and initiate adaptive mitigation responses.

(ii) At all times, vessels must maintain the maximum distance possible from concentrations of walruses or polar bears. Under no circumstances, other than an emergency, should any vessel approach within an 805-m (0.5-mi) radius of walruses or polar bears observed on ice. Under no circumstances, other than an emergency, should any vessel approach within 1,610 m (1 mi) of groups of walruses observed on land or within an 805-m (0.5-mi) radius of polar bears observed on land.

(iii) Vessel operators must take every precaution to avoid harassment of concentrations of feeding walruses when a vessel is operating near these

animals. Vessels should reduce speed and maintain a minimum 805-m (0.5-mi) operational exclusion zone around groups of 12 or more walruses encountered in the water. Vessels may not be operated in such a way as to separate members of a group of walruses from other members of the group. When weather conditions require, such as when visibility drops, vessels should adjust speed accordingly to avoid the likelihood of injury to walruses.

(iv) The transit of operational and support vessels through the specified geographic region is not authorized prior to July 1. This operating condition is intended to allow walruses the opportunity to disperse from the confines of the spring lead system and minimize interactions with subsistence walrus hunters. Variances to this operating condition may be issued by the Service on a case-by-case basis, based upon a review of seasonal ice conditions and available information on walrus and polar bear distributions in the area of interest.

(v) All vessels must avoid areas of active or anticipated subsistence hunting for walrus or polar bear as determined through community consultations.

(vi) We may require a monitor on the site of the activity or on board drillships, drill rigs, aircraft, icebreakers, or other support vessels or vehicles to monitor the impacts of Industry's activity on polar bear and Pacific walruses.

(3*) Operating conditions for aircraft.* (i) Operators of support aircraft should, at all times, conduct their activities at the maximum distance possible from concentrations of walruses or polar bears.

(ii) Under no circumstances, other than an emergency, should fixed wing aircraft operate at an altitude lower than 457 m (1,500 ft) within 805 m (0.5 mi) of walrus groups observed on ice, or within 1,610 m (1 mi) of walrus groups observed on land. Under no circumstances, other than an emergency, should rotary winged aircraft (helicopters) operate at an altitude lower than 914 m (3,000 ft) within 1,610 m (1 mi) of walrus groups observed on land. Under no circumstances, other than an emergency, should aircraft operate at an altitude lower than 457 m (1,500 ft) within 805 m (0.5 mi) of polar bears observed on ice or land. Helicopters may not hover or circle above such areas or within 805 m (0.5 mile) of such areas. When weather conditions do not allow a 457-m (1,500-ft) flying altitude, such as during severe storms or when cloud cover is low, aircraft may be operated below the required altitudes stipulated above. However, when aircraft are operated at altitudes below 457 m (1,500 ft) because of weather conditions, the operator must avoid areas of known walrus and polar bear concentrations and should take precautions to avoid flying directly over or within 805 m (0.5 mile) of these areas.

(iii) Plan all aircraft routes to minimize any potential conflict with active or anticipated walrus or polar bear hunting activity as determined through community consultations.

(4) *Additional mitigation measures for offshore exploration activities.* (i) Offshore exploration activities will be authorized only during the open-water season, defined as the period July 1 to November 30. Variances to the specified open-water season may be issued by the Service on a case-by-case basis, based upon a review of seasonal ice conditions and available information on walrus and polar bear distributions in the area of interest.

(ii) To avoid significant synergistic or cumulative effects from multiple oil and gas exploration activities on foraging or migrating walruses, operators must maintain a minimum spacing of 24 km (15 mi) between all active seismic source vessels and/or drill rigs during exploration activities. This does not include support vessels for these operations. No more than two simultaneous seismic operations and three offshore exploratory drilling operations will be authorized in the Chukchi Sea region at any time.

(iii) No offshore exploration activities will be authorized within a 64-km (40-mi) radius of the communities of Barrow, Wainwright, Point Lay, or Point Hope, unless provided for in a Service-approved, site-specific Plan of Cooperation as described in paragraph (a)(7) of this section.

(iv) A monitoring program acceptable to the Service will be required to estimate the number of walruses and polar bears in a proposed project area.

(v) Hanna Shoal Walrus Use Area (HSWUA). The HSWUA is a high use area for Pacific walruses (Figure 2). Due to the large number of walruses that could be encountered in the HSWUA from July through September, additional mitigation measures may be applied to activities within the HSWUA on a case-by-case basis. These mitigation measures include, but may not be limited to, seasonal restrictions, reduced vessel traffic, or rerouting of vessels. To the maximum extent practicable, aircraft supporting exploration activities shall avoid operating below 1,500 feet ASL over the HSWUA between July 1 and September 30.

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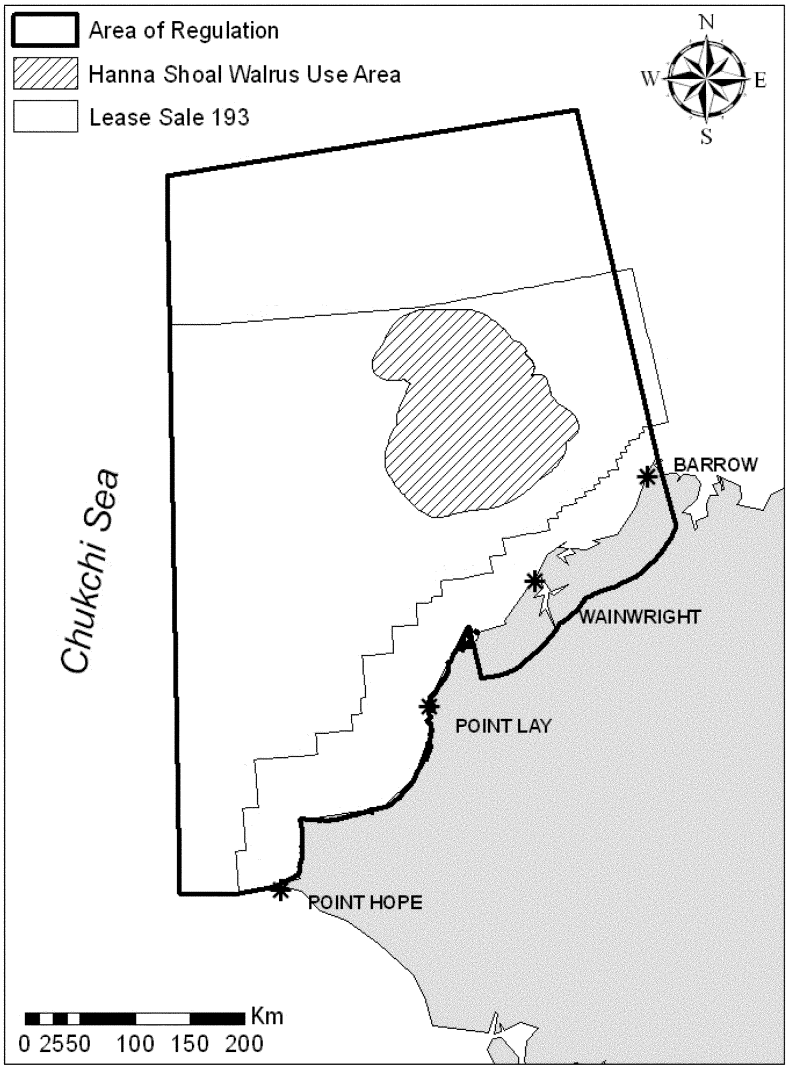

Figure 2. The combined Pacific walrus foraging and occupancy 50 percent utilization distribution polygon for the Hanna Shoal region that define the Walrus Hanna Shoal Use Area based on Jay *et al.* (2012) in relation to the Lease Sale 193 and the geographic region of the incidental take regulations.

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(5) *Additional mitigation measures for offshore seismic surveys.* Any offshore exploration activity expected to include the production of pulsed underwater sounds with sound source levels ≥160 dB re 1 μPa will be required to establish and monitor acoustic exclusion and disturbance zones and implement adaptive mitigation measures as follows:

(i) *Monitor zones.* Establish and monitor with trained marine mammal observers an acoustically verified exclusion zone for walruses surrounding seismic airgun arrays where the received level will be ≥ 180 dB re 1 μPa; an acoustically verified exclusion zone for polar bear surrounding seismic airgun arrays where the received level will be ≥ 190 dB re 1 μPa; and an acoustically verified walrus disturbance zone ahead of and perpendicular to the seismic vessel track where the received level will be ≥ 160 dB re 1 μPa.

(ii) *Ramp-up procedures.* For all seismic surveys, including airgun testing, use the following ramp-up procedures to allow marine mammals to depart the exclusion zone before seismic surveying begins:

(A) Visually monitor the exclusion zone and adjacent waters for the absence of polar bears and walruses for at least 30 minutes before initiating ramp-up procedures. If no polar bears or walruses are detected, you may initiate ramp-up procedures. Do not initiate ramp-up procedures at night or when you cannot visually monitor the exclusion zone for marine mammals.

(B) Initiate ramp-up procedures by firing a single airgun. The preferred airgun to begin with should be the smallest airgun, in terms of energy output (dB) and volume (in^3).

(C) Continue ramp-up by gradually activating additional airguns over a period of at least 20 minutes, but no longer than 40 minutes, until the desired operating level of the airgun array is obtained.

(iii) *Power down/Shutdown.* Immediately power down or shutdown the seismic airgun array and/or other acoustic sources whenever any walruses are sighted approaching close to or within the area delineated by the 180 dB re 1 μPa walrus exclusion zone, or polar bears are sighted approaching close to or within the area delineated by the 190 dB re 1 μPa polar bear exclusion zone. If the power down operation cannot reduce the received sound pressure level to 180 dB re 1 μPa (walrus) or 190 dB re 1 μPa (polar bear), the operator must immediately shutdown the seismic airgun array and/or other acoustic sources.

(iv) *Emergency shutdown.* If observations are made or credible reports are received that one or more walruses and/or polar bears are within the area of the seismic survey and are in an injured or mortal state, or are indicating acute distress due to seismic noise, the seismic airgun array will be immediately shutdown and the Service contacted. The airgun array will not be restarted until review and approval has been given by the Service. The ramp-up procedures provided in paragraph (a)(5)(ii) of this section must be followed when restarting.

(v) *Adaptive response for walrus aggregations.* Whenever an aggregation of 12 or more walruses are detected within an acoustically verified 160 dB re 1 μPa disturbance zone ahead of or perpendicular to the seismic vessel track, the holder of this Authorization must:

(A) Immediately power down or shutdown the seismic airgun array and/or other acoustic sources to ensure sound pressure levels at the shortest distance to the aggregation do not exceed 160–dB re 1 μPa; and

(B) Not proceed with powering up the seismic airgun array until it can be established that there are no walrus aggregations within the 160 dB zone based upon ship course, direction, and distance from last sighting. If shutdown was required, the ramp-up procedures provided in paragraph (a)(5)(ii) of this section must be followed when restarting.

(6) *Additional mitigation measures for onshore exploration activities.* (i) *Polar bear monitors.* If deemed appropriate by the Service, holders of a Letter of Authorization will be required to hire and train polar bear monitors to alert crew of the presence of polar bears and initiate adaptive mitigation responses.

(ii) *Efforts to minimize disturbance around known polar bear dens.* As part of potential terrestrial activities during the winter season, holders of a Letter of Authorization must take efforts to limit disturbance around known polar bear dens.

(A) *Efforts to locate polar bear dens.* Holders of a Letter of Authorization seeking to carry out onshore exploration activities in known or suspected polar bear denning habitat during the denning season (November to April) must make efforts to locate occupied polar bear dens within and near proposed areas of operation, utilizing appropriate tools, such as forward looking infrared (FLIR) imagery and/or polar bear scent trained dogs. All observed or suspected polar bear dens must be reported to the Service prior to the initiation of exploration activities.

(B) *Exclusion zone around known polar bear dens.* Operators must observe a 1-mile operational exclusion zone around all known polar bear dens during the denning season (November to April, or until the female and cubs leave the areas). Should previously unknown occupied dens be discovered within 1 mile of activities, work in the immediate area must cease and the Service contacted for guidance. The Service will evaluate these instances on a case-by-case basis to determine the appropriate action. Potential actions may range from cessation or modification of work to conducting additional monitoring, and the holder of the authorization must comply with any additional measures specified.

(7) *Mitigation measures for the subsistence use of walruses and polar bears.* Holders of Letters of Authorization must conduct their activities in a manner that, to the greatest extent practicable, minimizes adverse impacts on the availability of Pacific walruses and polar bears for subsistence uses.

(i) *Community Consultation.* Prior to receipt of a Letter of Authorization, applicants must consult with potentially affected communities and appropriate subsistence user organizations to discuss potential conflicts with subsistence hunting of walrus and polar bear caused by the location, timing, and methods of Industry operations and support activities (see § 18.114(c)(4) for details). If community concerns suggest that the Industry activities may have an adverse impact on the subsistence uses of these species, the applicant must address conflict avoidance issues through a Plan of Cooperation as described in paragraph (a)(7)(ii) of this section.

(ii) *Plan of Cooperation (POC).* Where prescribed, holders of Letters of Authorization will be required to develop and implement a Service-approved POC.

(A) The POC must include:

(*1*) A description of the procedures by which the holder of the Letter of Authorization will work and consult with potentially affected subsistence hunters; and

(*2*) A description of specific measures that have been or will be taken to avoid or minimize interference with subsistence hunting of walruses and polar bears and to ensure continued availability of the species for subsistence use.

(B) The Service will review the POC to ensure that any potential adverse effects on the availability of the animals are minimized. The Service will reject POCs if they do not provide adequate safeguards to ensure the least practicable adverse impact on the availability of walruses and polar bears for subsistence use.

(b) *Monitoring.* Depending on the siting, timing, and nature of Industry activities, holders of Letters of Authorization will be required to:

(1) Maintain trained, Service-approved, on-site observers to carry out monitoring programs for polar bears and walruses necessary for initiating adaptive mitigation responses.

(i) Marine Mammal Observers (MMOs) will be required on board all operational and support vessels to alert crew of the presence of walruses and polar bears and initiate adaptive mitigation responses identified in paragraph (a) of this section, and to carry out specified monitoring activities identified in the marine mammal monitoring and mitigation plan (see paragraph (b)(2) of this section) necessary to evaluate the impact of authorized activities on walruses, polar bears, and the subsistence use of these subsistence resources. The MMOs must have completed a marine mammal observer training course approved by the Service.

(ii) Polar bear monitors. Polar bear monitors will be required under the monitoring plan if polar bears are known to frequent the area or known polar bear dens are present in the area. Monitors will act as an early detection system concerning proximate bear activity to Industry facilities.

(2) Develop and implement a site-specific, Service-approved marine

mammal monitoring and mitigation plan to monitor and evaluate the effects of authorized activities on polar bears, walruses, and the subsistence use of these resources.

(i) The marine mammal monitoring and mitigation plan must enumerate the number of walruses and polar bears encountered during specified exploration activities, estimate the number of incidental takes that occurred during specified exploration activities (i.e., document immediate behavioral responses as well as longer term, when requested), and evaluate the effectiveness of prescribed mitigation measures.

(ii) Applicants must fund an independent peer review of proposed monitoring plans and draft reports of monitoring results after consultation with the Service. This peer review will consist of independent reviewers who have knowledge and experience in statistics, marine mammal behavior, and the type and extent of Industry operations. The applicant will provide the results of these peer reviews to the Service for consideration in final approval of monitoring plans and final reports. The Service will distribute copies of monitoring reports to appropriate resource management agencies and co-management organizations.

(3) Cooperate with the Service and other designated Federal, State, and local agencies to monitor the impacts of oil and gas exploration activities in the Chukchi Sea on walruses or polar bears. Where insufficient information exists to evaluate the potential effects of Industry activities on walruses, polar bears, and the subsistence use of these resources, holders of Letters of Authorization may be requested to participate in monitoring and/or research efforts in order to help the Service address these information needs and ensure the least practicable impact to these resources. These monitoring and research efforts will employ rigorous study designs and sampling protocols in order to provide useful information. As an example, operators could test new technologies during their activities that will be beneficial in minimizing disturbance to animals. Information gaps and needs in the Chukchi Sea include, but are not limited to:

(i) Distribution, abundance, movements, and habitat use patterns of walruses and polar bears in offshore environments;

(ii) Patterns of subsistence hunting activities by the Native Villages of Kivalina, Point Hope, Point Lay, Wainwright, and Barrow for walruses and polar bears;

(iii) Immediate and longer term (when possible) behavioral and other responses of walruses and polar bears to seismic airguns, drilling operations, vessel traffic, and fixed wing aircraft and helicopters;

(iv) Contaminant levels in walruses, polar bears, and their prey;

(v) Cumulative effects of multiple simultaneous operations on walruses and polar bears; and

(vi) Oil spill risk assessment for the marine and shoreline environment of walruses, polar bears, their prey, and important habitat areas (e.g., coastal haulouts and den sites).

(c) *Reporting requirements.* Holders of Letters of Authorization must report the results of specified monitoring activities to the Service's Alaska Regional Director (see 50 CFR 2.2 for address).

(1) *In-season monitoring reports*—(i) *Activity progress reports.* Operators must keep the Service informed on the progress of authorized activities by:

(A) Notifying the Service at least 48 hours prior to the onset of activities;

(B) Providing weekly progress reports of authorized activities noting any significant changes in operating state and or location; and

(C) Notifying the Service within 48 hours of ending activity.

(ii) *Walrus observation reports.* The operator must report, on a weekly basis, all observations of walruses during any Industry operation. Information within the observation report will include, but is not limited to:

(A) Date, time, and location of each walrus sighting;

(B) Number, sex, and age of walruses (if determinable);

(C) Observer name, company name, vessel name or aircraft number, LOA number, and contact information;

(D) Weather, visibility, and ice conditions at the time of observation;

(E) Estimated distance from the animal or group when initially sighted, at closest approach, and end of the encounter;

(F) Industry activity at time of sighting and throughout the encounter. If a seismic survey, record the estimated radius of the zone of ensonification;

(G) Behavior of animals at initial sighting, any change in behavior during the observation period, and distance from the observers associated with those behavioral changes;

(H) Detailed description of the encounter;

(I) Duration of the encounter;

(J) Duration of any behavioral response (e.g., time and distance of a flight response) and;

(K) Actions taken.

(iii) *Polar bear observation reports.* The operator must report, within 24 hours, all observations of polar bears during any Industry operation. Information within the observation report will include, but is not limited to:

(A) Date, time, and location of observation;

(B) Number, sex, and age of bears (if determinable);

(C) Observer name, company name, vessel name, LOA number, and contact information;

(D) Weather, visibility, and ice conditions at the time of observation;

(E) Estimated closest point of approach for bears from personnel and/or vessel/facilities;

(F) Industry activity at time of sighting, and possible attractants present;

(G) Behavior of animals at initial sighting and after contact;

(H) Description of the encounter;

(I) Duration of the encounter; and

(J) Actions taken.

(iv) *Notification of incident report.* Reports should include all information specified under the species observation report, as well as a full written description of the encounter and actions taken by the operator. The operator must report to the Service within 24 hours:

(A) Any incidental lethal take or injury of a polar bear or walrus; and

(B) Observations of walruses or polar bears within prescribed mitigation monitoring zones.

(2) *After-action monitoring reports.* The results of monitoring efforts identified in the marine mammal monitoring and mitigation plan must be submitted to the Service for review within 90 days of completing the year's activities. Results must include, but are not limited to, the following information:

(i) A summary of monitoring effort including: Total hours, total distances, and distribution through study period of each vessel and aircraft;

(ii) Analysis of factors affecting the visibility and detectability of walruses and polar bears by specified monitoring;

(iii) Analysis of the distribution, abundance, and behavior of walrus and polar bear sightings in relation to date, location, ice conditions, and operational state;

(iv) Estimates of take based on the number of animals encountered/kilometer of vessel and aircraft operations by behavioral response (no response, moved away, dove, etc.), and animals encountered per day by behavioral response for stationary drilling operations; and

(v) Raw data in electronic format (i.e., Excel spreadsheet) as specified by the Service in consultation with Industry representatives.

§ 18.119 What are the information collection requirements?

(a) The Office of Management and Budget has approved the collection of information contained in this subpart and assigned control number 1018–0070. You must respond to this information collection request to obtain a benefit pursuant to section 101(a)(5) of the Marine Mammal Protection Act. We will use the information to:

(1) Evaluate the application and determine whether or not to issue specific Letters of Authorization.

(2) Monitor impacts of activities conducted under the Letters of Authorization.

(b) You should direct comments regarding the burden estimate or any other aspect of this requirement to the Information Collection Clearance Officer, U.S. Fish and Wildlife Service, Department of the Interior, Mail Stop 2042–PDM, 1849 C Street NW., Washington, DC 20240.

Dated: May 30, 2013.

Rachel Jacobson,

Principal Deputy Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 2013–13725 Filed 6–11–13; 8:45 am]

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Part III

Bureau of Consumer Financial Protection

12 CFR Part 1026

Ability-to-Repay and Qualified Mortgage Standards Under the Truth in Lending Act (Regulation Z); Final Rule

BUREAU OF CONSUMER FINANCIAL PROTECTION

12 CFR Part 1026

[Docket No. CFPB–2013–0002]

RIN 3170–AA34

Ability-to-Repay and Qualified Mortgage Standards Under the Truth in Lending Act (Regulation Z)

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Final rule; official interpretations.

SUMMARY: The Bureau of Consumer Financial Protection (Bureau) is amending Regulation Z, which implements the Truth in Lending Act (TILA). Regulation Z generally prohibits a creditor from making a mortgage loan unless the creditor determines that the consumer will have the ability to repay the loan. The final rule provides an exemption to these requirements for creditors with certain designations, loans pursuant to certain programs, certain nonprofit creditors, and mortgage loans made in connection with certain Federal emergency economic stabilization programs. The final rule also provides an additional definition of a qualified mortgage for certain loans made and held in portfolio by small creditors and a temporary definition of a qualified mortgage for balloon loans. Finally, the final rule modifies the requirements regarding the inclusion of loan originator compensation in the points and fees calculation.

DATES: This rule is effective January 10, 2014.

FOR FURTHER INFORMATION CONTACT: Jennifer B. Kozma or Eamonn K. Moran, Counsels; Thomas J. Kearney or Mark Morelli, Senior Counsels; or Stephen Shin, Managing Counsel, Office of Regulations, at (202) 435–7700.

SUPPLEMENTARY INFORMATION:

I. Summary of the Final Rule

The Bureau is issuing this final rule to adopt certain exemptions, modifications, and clarifications to TILA's ability-to-repay requirements. TILA section 129C, as added by sections 1411, 1412, and 1414 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), generally requires creditors to make a reasonable, good faith determination of a consumer's ability to repay a mortgage loan and creates a presumption of compliance with these ability-to-repay requirements for certain loans designated as ''qualified mortgages.'' On January 10, 2013, the Bureau issued a final rule (the 2013 ATR Final Rule) to implement these ability-to-repay requirements and qualified mortgage provisions. *See* 78 FR 6407 (Jan. 30, 2013). At the same time, the Bureau issued a proposed rule (the 2013 ATR Proposed Rule or Bureau's proposal) related to certain proposed exemptions, modifications, and clarifications to the ability-to-repay requirements. *See* 78 FR 6621 (Jan. 30, 2013). This final rule addresses the issues put forth for public comment in the 2013 ATR Proposed Rule. See part II.B below and part II.B–F of the 2013 ATR Final Rule for a complete discussion of the statutory and regulatory background to the ability-to-repay requirements.

Loan Originator Compensation and the Points and Fees Calculation

The Dodd-Frank Act generally provides that points and fees on a qualified mortgage may not exceed 3 percent of the loan balance and that points and fees in excess of 5 percent will trigger the protections for high-cost mortgages under the Home Ownership and Equity Protection Act (HOEPA).[1] The Dodd-Frank Act also included a provision requiring that loan originator compensation be counted toward these thresholds, even if it is not paid up-front by the consumer directly to the loan originator.

The Bureau had solicited comment on how to apply the statutory requirements in situations in which payments pass from one party to another over the course of a mortgage transaction. The Bureau was particularly concerned about situations in which the creditor pays compensation to a mortgage broker or its own loan originator employees because there is no simple way to determine whether the compensation is paid from money the creditor collected from up-front charges to the consumer (which would already be counted against the points and fees thresholds) or from the interest rate on the loan (which would not be counted toward the thresholds).

The final rule excludes from points and fees loan originator compensation paid by a consumer to a mortgage broker when that payment has already been counted toward the points and fees thresholds as part of the finance charge under § 1026.32(b)(1)(i). The final rule also excludes from points and fees compensation paid by a mortgage broker to an employee of the mortgage broker because that compensation is already included in points and fees as loan originator compensation paid by the consumer or the creditor to the mortgage broker.

The final rule excludes from points and fees compensation paid by a creditor to its loan officers. The Bureau concluded that there were significant operational challenges to calculating individual employee compensation accurately early in the loan origination process, and that those challenges would lead to anomalous results for consumers. In addition, the Bureau concluded that structural differences between the retail and wholesale channels lessened risks to consumers. The Bureau will continue to monitor the market to determine if additional protections are necessary and evaluate whether there are different approaches for calculating retail loan officer compensation consistent with the purposes of the statute.

The final rule retains an ''additive'' approach for calculating loan originator compensation paid by a creditor to a loan originator other than an employee of creditor. Under the additive approach, § 1026.32(b)(1)(ii) requires that a creditor include in points and fees compensation paid by the creditor to a mortgage broker, in addition to up-front charges paid by the consumer to the creditor that are included in points and fees under § 1026.32(b)(1)(i).

Exemptions for Certain Creditors and Lending Programs

Certain creditors and nonprofits. The final rule provides an exemption from the ability-to-repay requirements for extensions of credit made by certain types of creditors. Creditors designated by the U.S. Department of the Treasury as Community Development Financial Institutions and creditors designated by the U.S. Department of Housing and Urban Development as either a Community Housing Development Organization or a Downpayment Assistance Provider of Secondary Financing are exempt from the ability-to-repay requirements, under certain conditions. The final rule also generally exempts creditors designated as nonprofit organizations under section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3)) that extend credit no more than 200 times annually, provide credit only to low-to-moderate income consumers, and follow their own written procedures to determine that consumers have a reasonable ability to repay their loans.

Credit extended pursuant to certain lending programs. The final rule provides an exemption from the ability-to-repay requirements for extensions of

[1] *See* title I subtitle B of the Riegle Community Development and Regulatory Improvement Act of 1994, Public Law 103–325, 108 Stat. 2160 (Jan. 25, 1994).

credit made pursuant to programs administered by a housing finance agency and for an extension of credit made pursuant to an Emergency Economic Stabilization Act program, such as extensions of credit made pursuant to a State Hardest Hit Fund program.

Small Creditor Portfolio and Balloon-Payment Qualified Mortgages

The final rule contains several provisions that are designed to facilitate compliance and preserve access to credit from small creditors, which are defined as creditors with no more than $2 billion in assets that (along with affiliates) originate no more than 500 first-lien mortgages covered under the ability-to-repay rules per year. The Bureau had previously exercised authority under the Dodd-Frank Act to allow certain balloon-payment mortgages to be designated as qualified mortgages if they were originated and held in portfolio by small creditors operating predominantly in rural or underserved areas. In this final rule, the Bureau is:

- Adopting a new, fourth category of qualified mortgages for certain loans originated and held in portfolio for at least three years (subject to certain limited exceptions) by small creditors, even if they do not operate predominantly in rural or underserved areas. The loans must meet the general restrictions on qualified mortgages with regard to loan features and points and fees, and creditors must evaluate consumers' debt-to-income ratio or residual income. However, the loans are not subject to a specific debt-to-income ratio as they would be under the general qualified mortgage definition.
- Raising the threshold defining which qualified mortgages receive a safe harbor under the ability-to-repay rules for loans that are made by small creditors under the balloon-loan or small creditor portfolio categories of qualified mortgages. Because small creditors often have higher cost of funds, the final rule shifts the threshold separating qualified mortgages that receive a safe harbor from those that receive a rebuttable presumption of compliance with the ability-to-repay rules from 1.5 percentage points above the average prime offer rate (APOR) on first-lien loans to 3.5 percentage points above APOR.
- Providing a two-year transition period during which small creditors that do not operate predominantly in rural or underserved areas can offer balloon-payment qualified mortgages if they hold the loans in portfolio. During the two-period transition period, the Bureau intends to study whether the definitions of ''rural'' or ''underserved'' should be adjusted and to work with small creditors to transition to other types of products, such as adjustable-rate mortgages, that satisfy other qualified mortgage definitions.

The ability-to-repay rules as revised by this final rule will take effect on January 10, 2014, along with various other rules implementing new mortgage protections under the Dodd-Frank Act.

II. Background

A. Mortgage Market Background

The mortgage market is the single largest market for consumer financial products and services in the United States. In 2007 and 2008 this market collapsed, greatly diminishing the wealth of millions of American consumers and sending the economy into a severe recession. A primary cause of the collapse was the steady deterioration of credit standards in mortgage lending. Evidence demonstrates that many mortgage loans were made solely against collateral and without consideration of ability to repay, particularly in the markets for ''subprime'' and ''Alt-A'' products, which more than doubled from $400 billion in originations in 2003 to $830 billion in originations in 2006.[2] Subprime products were sold primarily to consumers with poor or no credit history, while Alt-A loans were sold primarily to consumers who provided little or no documentation of income or other evidence of repayment ability.[3]

Because subprime and Alt-A loans involved additional risk, they were typically more expensive to consumers than ''prime'' mortgage loans, although many of them had very low introductory interest rates. While housing prices continued to increase, it was relatively easy for consumers to refinance their existing loans into more affordable products to avoid interest rate resets and other adjustments. When housing prices began to decline in 2005, however, refinancing became more difficult and delinquency rates on subprime and Alt-A products increased dramatically.[4] By the summer of 2006, 1.5 percent of loans less than a year old were in default, and this figure peaked at 2.5 percent in late 2007.[5] As the economy worsened, the rates of serious delinquency (90 or more days past due or in foreclosure) for the subprime and Alt-A products began a steep increase from approximately 10 percent in 2006, to 20 percent in 2007, to over 40 percent in 2010.[6] Although the mortgage market is recovering, consumers today continue to feel the effects of the financial crisis.

Community-Focused Lending Programs

While governmental and nonprofit programs have always been an important source of assistance for low- to moderate-income (LMI) consumers, these programs have taken on even greater significance in light of current tight mortgage credit standards and Federal initiatives to stabilize the housing market. There are a variety of programs designed to assist LMI consumers with access to homeownership. These programs are generally offered through a nonprofit entity, local government, or a housing finance agency (HFA). These programs play an important role in the housing sector of the economy.

Types of financial assistance available. Community-focused lending programs typically provide LMI consumers with assistance ranging from housing counseling services to full mortgage loan financing. Some programs offer financial assistance through land trust programs, in which the consumer leases the real property and takes ownership of only the improvements. Many organizations provide ''downpayment assistance'' in connection with mortgage loan financing. This can be a gift, grant, or loan to the consumer to assist with the consumer's down payment, or to pay for some of the closing costs. These programs often rely on subsidies from Federal government funds, local government funds, foundations, or

[2] Inside Mortg. Fin., *The 2011 Mortgage Market Statistical Annual* (2011).

[3] There is evidence that some consumers who would have qualified for ''prime'' loans were steered into subprime loans as well. The Federal Reserve Board on July 18, 2011 issued a consent cease and desist order and assessed an $85 million civil money penalty against Wells Fargo & Company of San Francisco, a registered bank holding company, and Wells Fargo Financial, Inc., of Des Moines. The order addresses allegations that Wells Fargo Financial employees steered potential prime-eligible consumers into more costly subprime loans and separately falsified income information in mortgage applications. In addition to the civil money penalty, the order requires that Wells Fargo compensate affected consumers. *See* Press Release, Federal Reserve Board (July 20, 2011), *available at: http://www.federalreserve.gov/newsevents/press/enforcement/20110720a.htm.*

[4] U.S. Fin. Crisis Inquiry Comm'n, *The Financial Crisis Inquiry Report: Final Report of the National Commission on the Causes of the Financial and Economic Crisis in the United States* at 215–217 (Official Gov't ed. 2011) (FCIC Report), *available at: http://www.gpo.gov/fdsys/pkg/GPO-FCIC/pdf/GPO-FCIC.pdf.*

[5] *FCIC Report* at 215. CoreLogic Chief Economist Mark Fleming told the FCIC that the early payment default rate ''certainly correlates with the increase in the Alt-A and subprime shares and the turn of the housing market and the sensitivity of those loan products.'' *Id.*

[6] *FCIC Report* at 217.

employer funding.[7] For example, many of these programs rely on funds provided through the HUD Home Investment Partnerships Program (HOME Program).[8]

Some programs offer first-lien mortgage loans designed to meet the needs of LMI consumers. These first-lien mortgage loans may have a discounted interest rate or limited origination fees or may permit high loan-to-value ratios. Many programs offer subordinate financing. Subordinate-financing options may be simple, such as a relatively inexpensive subordinate-lien loan to pay for closing costs. Other methods of subordinate financing may be complex. For example, one HFA program offers a 30-year, fixed-rate, subordinate-lien mortgage loan through partner creditors, with interest-only payments for the first 11 years of the loan's term, and with an interest subsidy for the LMI consumer, resulting in a graduated monthly payment between the fifth and eleventh year of the loan; an additional 30-year deferred, 0 percent subordinate-lien mortgage loan is extended by the HFA equal to the amount of the subsidy.[9] Some of the loans offered by these programs, whether first-lien or subordinate-financing, are structured as hybrid grant products that are commonly forgiven.

Housing finance agencies. For over 50 years, HFAs have provided LMI consumers with opportunities for affordable homeownership.[10] HFAs are governmental entities, chartered by either a State or a municipality, that engage in diverse housing financing activities for the promotion of affordable housing. Some HFAs are chartered to promote affordable housing goals across an entire State, while others' jurisdiction extends to only particular cities or counties.[11] Many of the State and Federal programs HFAs administer do not provide administrative funds; others provide limited administrative funds. Most HFAs operate independently and do not receive State operating funds. These agencies are generally funded through tax-exempt bonds but may receive funding from Federal, State, or other sources.[12] HFAs issue these tax-exempt bonds, also known as mortgage revenue bonds, and use the proceeds of the bond sale to finance affordable mortgage loans to LMI consumers. As of June 2012, the 51 State HFAs (including the District of Columbia) had $107 billion in outstanding tax-free municipal debt available. These mortgage revenue bonds funded approximately 100,000 first-time homeowners per year. HFAs may also receive funding through Federal programs, such as the HOME Program, which is the largest Federal block grant for affordable housing.[13]

HFAs employ several methods of promoting affordable homeownership. These agencies may partner with local governments to develop and implement long-term community-development strategies. For example, HFAs may provide tax credits to companies that build or rehabilitate affordable housing.[14] These agencies may also administer affordable housing trust funds or other State programs to facilitate the affordable housing development.[15] Many HFAs also provide education, counseling, or training courses to first-time or LMI consumers.

HFAs also provide financial assistance directly to consumers. Typically, HFAs offer the first-lien mortgage loan, subordinate financing, and downpayment assistance programs described above. HFAs may also establish pooled loss reserves to self-insure mortgage loans originated pursuant to the program, thereby permitting LMI consumers to avoid private mortgage insurance. HFAs may also provide other assistance to LMI consumers, such as mortgage loan payment subsidies or assistance with the up-front costs of a mortgage loan. In 2010, HFAs provided about $10 billion in affordable financing.[16] In 2010, 89 percent of HFAs provided down payment assistance loan or grant assistance and 57 percent of HFAs provided assistance in conjunction with programs offered by the Federal Housing Administration (FHA) or the U.S. Department of Agriculture (USDA).[17] However, HFAs generally do not provide direct financing to LMI consumers. Many HFAs are prohibited by law from directly extending credit in an effort by State governments to avoid competing with the private sector. HFAs generally partner with creditors, such as local banks, that extend credit pursuant to the HFA's program guidelines. Most HFA programs are ''mortgage purchase'' programs in which the HFA establishes program requirements (*e.g.,* income limits, purchase price limits, interest rates, points and term limits, underwriting standards, etc.), and agrees to purchase loans made by private creditors that meet these requirements.

Many HFAs expand on the underwriting standards of GSEs or Federal government agencies by applying even stricter underwriting standards than these guidelines or the ability-to-repay requirements, such as requiring mandatory counseling for all first-time homebuyers and strong loan servicing. For example, the State of New York Mortgage Agency (SONYMA)'s underwriting requirements generally include a two-year, stable history of earned income, a monthly payment-to-income ratio not to exceed 40 percent, a monthly debt-to-income ratio not to exceed 45 percent, and review of the consumer's entire credit profile to determine acceptable credit.[18]

HFAs extend credit only after conducting a lengthy and thorough analysis of a consumer's ability to repay. HFAs generally employ underwriting requirements that are uniquely tailored to meet the needs of LMI consumers, and which often account for nontraditional underwriting criteria, extenuating circumstances, and other elements that are indicative of

[7] Abigail Pound, *Challenges and Changes in Community-Based Lending for Homeownership,* NeighborWorks America, Joint Center for Housing Studies of Harvard University (Feb. 2011), *available at: http://www.jchs.harvard.edu/sites/jchs.harvard.edu/files/w11-2_pound.pdf.*

[8] The HOME Investment Partnerships Program is authorized under title II of the Cranston-Gonzalez National Affordable Housing Act of 1990, Public Law 101–625, 104 Stat. 4079 (1990). *See* 24 CFR 92.1 through 92.618.

[9] See *http://www.mhp.net/homeownership/homebuyer/soft_second_works.php,* describing the SoftSecond program offered by the Massachusetts Housing Partnership.

[10] The first State housing finance agency was established in New York in 1960. *See* New York State Housing Finance Agency Act, 1960 Laws of New York, 183rd Session, Chap. 671.

[11] For example, the Louisiana Housing Corporation administers affordable housing programs across all of Louisiana, while The Finance Authority of New Orleans administers programs only in Orleans Parish. *See www.lhfa.state.la.us* and *www.financeauthority.org.*

[12] Bonds issued by HFAs are tax-exempt if the proceeds are used to provide assistance to first-time or LMI-homebuyers. *See* 26 U.S.C. 143.

[13] *See www.hud.gov/homeprogram.*

[14] The Tax Reform Act of 1986, Public Law 99–514, 100 Stat. 2085 (1986), included the Low-Income Housing Tax Credit Program. Under this program, the IRS provides tax credits to HFAs. HFAs may transfer these tax credits to developers of affordable housing. Developers then sell these credits to fund the development program. *See http://portal.hud.gov/hudportal/HUD?src=/program_offices/comm_planning/affordablehousing/training/web/lihtc/basics.*

[15] The Massachusetts Affordable Housing Trust Fund provides funds to governmental subdivisions, nonprofit organizations, and other entities seeking to provide for the development of affordable housing. *See www.masshousing.com.* New York State's Mitchell-Lama program provides subsidies such as property tax exemptions to affordable housing developers. *See http://www.nyshcr.org/Programs/mitchell-lama/.*

[16] National Council of State Housing Agencies, *State HFA Factbook* (2010), p. 33.

[17] *Id.* at 21–22, 35–36.

[18] *See* State of New York Mortgage Agency (SONYMA) Credit and Property Underwriting Notes, *available at: http://www.nyshcr.org/assets/documents/1006.pdf.*

creditworthiness, ability to repay, and responsible homeownership. In certain circumstances, some HFAs require the consideration of compensating factors and other elements that are different from the factors required to be considered and verified under the ability-to-repay requirements. For example, the Connecticut Housing Finance Agency (CHFA)'s underwriting requirements require the consideration of certain compensating factors (*e.g.,* ability to make a large down payment, demonstrated ability to accumulate savings, substantial documented cash reserves, etc.) for consumers with debt ratios that exceed the maximum CHFA monthly payment-to-income and debt-to-income ratio limits.[19] In addition, to be eligible for Virginia Housing Development Authority (VHDA) conventional financing, a consumer must demonstrate the willingness and ability to repay the mortgage debt and creditors must consider: Employment and income; credit history; sufficient funds to close; monthly housing expenses; and monthly payment-to-income and debt-to-income ratios.[20] VHDA underwriting guidelines allow delegated underwriters to approve exceptions to the above debt-to-income ratios, provided that the ratios do not exceed 2 percent above the guidelines. The exceptions must be justified with strong compensating factors, which must indicate that the consumer can afford the repayment of the increased debt.[21] Through careful and regular oversight, however, HFAs help ensure that their lenders follow the HFAs' strict underwriting standards.

Private organizations. While entities such as HFAs develop and finance affordable housing programs, these mortgage loans are generally extended by private organizations. These organizations often are structured as nonprofit 501(c)(3) organizations. Under Internal Revenue Code section 501(c)(3), the designation is for nonprofit, tax-exempt, charitable organizations not operated for the benefit of private interests.[22] Under Federal tax law, 501(c)(3) organizations are restricted from lobbying activities, while 501(c)(4) organizations, which must exist to promote social welfare, may engage in political campaigning and lobbying.[23] Most organizations that provide support to LMI consumers are structured as 501(c)(3) organizations. However, some organizations are structured as nonprofit 501(c)(4) organizations.

Various Federal programs establish eligibility requirements and provide ongoing monitoring of specific types of creditors that receive Federal grants and other support. For example, Community Development Financial Institutions (CDFIs) are approved by the U.S. Department of the Treasury (Treasury Department) to receive monetary awards from the Treasury Department's CDFI Fund, which was established to promote capital development and growth in underserved communities. Promoting homeownership and providing safe lending alternatives are among the Fund's main goals. The Treasury Department created the CDFI designation to identify and support small-scale creditors that are committed to community-focused lending but have difficulty raising the capital needed to provide affordable housing services.[24] CDFIs may operate on a for-profit or nonprofit basis, provided the CDFI has a primary mission of promoting community development.[25] These programs are also subject to other eligibility requirements.[26] As of July 2012, there were 999 such organizations in the U.S., 62 percent of which were classified as Community Development (CD) Loan Funds and 22 percent as CD Credit Unions, while the rest were CD Banks, Thrifts, or CD Venture Capital Funds.[27]

The U.S. Department of Housing and Urban Development (HUD) may designate nonprofits engaging in affordable housing activities as Downpayment Assistance through Secondary Financing Providers (DAPs).[28] HUD established this designation as part of an effort to promote nonprofit involvement in affordable housing programs.[29] HUD-approved nonprofits may participate in FHA single-family programs that allow them to purchase homes at a discount, finance FHA-insured mortgages with the same terms and conditions as owner-occupants, or be able to finance secondary loans for consumers obtaining FHA-insured mortgages.[30] A DAP must be approved by HUD if it is a nonprofit or nonprofit instrumentality of government that provides downpayment assistance as a lien in conjunction with an FHA first mortgage; government entity DAPs and gift programs do not require approval.[31] As of May 2013 HUD listed 228 nonprofit agencies and nonprofit instrumentalities of government in the U.S. that are authorized to provide secondary financing.[32] HUD performs field reviews and requires annual reports of participating nonprofit agencies. Additionally, HUD's quality control plan requires periodic review for deficient policies and procedures and corrective actions. These approval and subsequent review procedures are intended to ensure that DAPs operate in compliance with HUD requirements and remain financially viable.[33] However, HUD recognizes that these nonprofits have limited resources and gives consideration to DAP viability when crafting regulations.[34]

Creditors may also be certified by HUD as Community Housing

[19] *See* Connecticut Housing Finance Agency Operating Manual, Section 5—Underwriting, *available at: http://www.chfa.org/content/CHFA%20Documents/Operating%20Manual%20-%20Section%2005%20Underwriting.pdf.*

[20] *See* Virginia Housing Development Authority Origination Guide, Section 2.3 Underwriting Requirements (Aug. 2011), *available at: http://www.vhda.com/BusinessPartners/Lenders/LoanInfoGuides/Loan%20Information%20and%20Guidelines/OriginationGuide.pdf.*

[21] *See id.*

[22] *See http://www.irs.gov/Charities-&-Non-Profits/Charitable-Organizations/Exemption-Requirements-Section-501(c)(3)-Organizations.*

[23] *See http://www.irs.gov/Charities-&-Non-Profits/Other-Non-Profits/Social-Welfare-Organizations.*

[24] *See* 68 FR 5704 (Feb. 4, 2003).

[25] *See* 12 CFR 1805.201(b).

[26] *Id.* Treasury Department eligibility requirements for CDFIs stipulate that an approved organization must: Be a legal entity at the time of certification application; have a primary mission of promoting community development; be a financing entity; primarily serve one or more target markets; provide development services in conjunction with its financing activities; maintain accountability to its defined target market; and be a non-government entity and not be under control of any government entity (Tribal governments excluded).

[27] *See http://www.cdfifund.gov/docs/certification/cdfi/CDFI List-07-31-12.xls.*

[28] *See* 24 CFR 200.194.

[29] ''Nonprofit organizations are important participants in HUD's efforts to further affordable housing opportunities for low- and moderate-income persons through the FHA single family programs. FHA's single family regulations recognize a special role for nonprofit organizations in conjunction with the . . . provision of secondary financing.'' *See* 67 FR 39238 (June 6, 2002).

[30] DAPs generally rely on FHA program guidelines for underwriting purposes, but have additional requirements for determining eligibility for assistance. For example, the Hawaii Homeownership Center is a HUD-approved DAP with separate eligibility criteria, *available at: http://www.hihomeownership.org/pdf/DPAL5_FAQ_JAN2013.pdf.*

[31] *See http://portal.hud.gov/hudportal/HUD?src=/program_offices/housing/sfh/np/sfhdap01.*

[32] *See https://entp.hud.gov/idapp/html/f17npdata.cfm.*

[33] ''It is vital that the Department periodically and uniformly assess the management and financial ability of participating nonprofit agencies to ensure they are not overextending their capabilities and increasing HUD's risk of loss as a mortgage insurance provider.'' 65 FR 9285, 9286 (Feb. 24, 2000).

[34] ''HUD continues to strongly encourage the participation of nonprofit organizations, including community and faith-based organizations, in its programs. This proposed rule is not designed to place particular burdens on participation by nonprofit organizations. Rather, the proposed rule is designed to ensure that nonprofit organizations have the capacity, experience, and interest to participate in HUD's housing programs.'' 69 FR 7324, 7325 (Feb. 13, 2004).

Development Organizations (CHDOs) in connection with HUD's HOME Program, which provides grants to fund a wide range of activities that promote affordable homeownership.[35] HUD Participating Jurisdictions confer CHDO certification only on community-focused nonprofits that are both dedicated to furthering a community's affordable housing goals and capable of complying with the requirements of the HOME Program.[36] Creditors designated as CHDOs are eligible to receive special CHDO set-aside funds from the HOME Program to fund local homebuyer assistance programs.[37] Applicants seeking CHDO status must meet rigorous requirements. For example, a CHDO must be designated as a nonprofit under section 501(c)(3) or (c)(4) of the Internal Revenue Code, adhere to strict standards of financial accountability, have among its purposes the provision of decent and affordable housing for LMI consumers, maintain accountability to the community, and have a proven record of capably and effectively serving low-income communities.[38] After the CHDO designation is obtained, CHDO creditors must operate under the supervision of a Participating Jurisdiction and in accordance with the requirements of the HOME Program.[39] HUD conducts annual performance reviews to determine whether funds have been used in accordance with program requirements.[40] While HUD continues to support affordable housing programs involving CHDOs, current market conditions have affected CHDO viability.[41]

CDFIs and CHDOs that provide mortgage loans generally employ underwriting guidelines tailored to the needs of LMI consumers. Unlike creditors that rely on industry-wide underwriting guidelines, which generally do not account for the unique credit characteristics of LMI consumers, CDFI and CHDO underwriting requirements include a variety of compensating factors. For example, these creditors often consider personal narratives explaining prior financial difficulties, such as gaps in employment or negative credit history.[42] Others consider the amount of time a consumer spends working on the construction or rehabilitation of affordable homes.[43] Some creditors also consider a consumer's general reputation, relying on references from a landlord or persons with whom the consumer does business.[44] In these transactions, a CDFI or CHDO may determine that the strength of these compensating characteristics outweigh weaknesses in other underwriting factors, such as negative credit history or irregular income. Including these compensating factors in the underwriting process enables CDFIs and CHDOs to more appropriately underwrite LMI consumers.

Nonprofit creditors may engage in community-focused lending without obtaining one of the designations described above. Such nonprofits often rely on HFA or Federal programs for funding, lending guidelines, and other support. However, some nonprofits offer credit to LMI consumers independent of these State or Federal programs. For example, nonprofits may make mortgage loans in connection with a GSE affordable housing program. The Federal Home Loan Bank (FHLB) System, Federal National Mortgage Association (Fannie Mae), and Federal Home Loan Mortgage Corporation (Freddie Mac) offer several programs to support affordable housing by facilitating mortgage financing for LMI consumers. For example, the FHLB Affordable Housing Program provides grants to member banks to fund programs that assist with closing costs or down payments, buy down principal amounts or interest rates, refinance an existing loan, or assist with rehabilitation or construction costs.[45] Fannie Mae and Freddie Mac also offer two programs focused on community-focused lending.[46]

Other options exist for nonprofits seeking to develop and fund community-focused lending programs. For example, a nonprofit may originate mortgage loans to LMI consumers and subsequently sell the loans to a bank, credit union, or other investor as part of a Community Reinvestment Act partnership program.[47] Other nonprofits may operate a limited affordable housing assistance fund, funded entirely by private donations, under which LMI consumers may obtain subordinate financing. Nonprofits such as these often rely on the underwriting performed by the creditor for the first-lien mortgage loan, which is often a bank or credit union, to process, underwrite, and approve the LMI consumer's application. In addition, some nonprofits are self-supporting and offer full financing to LMI consumers. These nonprofits often establish lending programs with unique guidelines, such as requirements that LMI consumers devote a minimum number of hours towards the construction of affordable housing.

Homeownership Stabilization and Foreclosure Prevention Programs

During the early stages of the financial crisis the mortgage market significantly

[35] *See http://portal.hud.gov/hudportal/HUD?src=/program_offices/comm_planning/affordablehousing/programs/home.*

[36] ''The Department believes that there was specific statutory intent to create an entitlement for community-based nonprofit organizations that would own, sponsor or develop HOME assisted housing. While partnerships with State and local government are critical to the development of affordable housing, these organizations are viewed as private, independent organizations separate and apart from State or local governments. One of the major objectives of the Department's technical assistance program is to increase the number of capable, successful CHDOs able and willing to use the CHDO set-aside [fund].'' 61 FR 48736, 48737 (Sept. 16, 1996).

[37] *See* 24 CFR 92.300 through 92.303.

[38] *See* 24 CFR 92.2.

[39] For example, no more than 5 percent of a Participating Jurisdiction's fiscal year HOME allocation may be used for CHDO operating expenses. 24 CFR 92.208(a).

[40] *See* 24 CFR 92.550 through 92.552.

[41] ''[Participating jurisdictions] have encountered new challenges in administering their programs and in managing their growing portfolios of older HOME projects. These challenges include reduced availability of states or local funding sources, reduced private lending, changes in housing property standards, and energy codes and reductions in states and local government workforces throughout the Nation. These challenges have been magnified by current housing and credit market conditions.'' 76 FR 78343, 78345 (Dec. 16, 2011).

[42] Neighborworks Anchorage, which is designated as both a CDFI and CHDO, requires letters of explanation regarding gaps in employment or derogatory credit history. *See http://www.nwanchorage.org/home-ownership/buying-home/getting-loan-affordable-loans-lending-programs.*

[43] The Community Development Corporation of Brownsville, which is designated as a CHDO, requires consumers to contribute 11 months of labor, or ''sweat equity,'' as part of the approval process. *See http://www.cdcb.org/h-h-programs.html#programs2.* St. Lucie Habitat for Humanity, which is designated as a CHDO, requires 300 hours of labor as part of the approval process. *See http://stluciehabitat.org/#.*

[44] Habitat for Humanity affiliates, many of which are designated as a CHDO or CDFI, consider references from current and former landlords, creditors, and others. *See* Habitat for Humanity Affiliate Operations Manual, *available at: http://www.medinahabitat.org/files/AffilOpFamilySelect.pdf.*

[45] The Federal Home Loan Bank of Des Moines provides funds for member bank programs related to rural homeownership, urban first-time homebuyers, and Native American homeownership. *See http://www.fhlbdm.com/community-investment/down-payment-assistance-programs/.* The Federal Home Loan Bank of Chicago provides funds for member bank programs related to down payment and closing cost assistance or eligible rehabilitation costs for the purchase of a home. *See http://ci.fhlbc.com/Grant_Pgms/DPP.shtml.*

[46] Fannie Mae offers first-lien mortgage loans through the My Community Mortgage program and subordinate-lien loans through the Community Seconds program. Freddie Mac offers both first- and subordinate-lien mortgage loans through the Home Possible program.

[47] Under the Community Reinvestment Act (12 U.S.C. 2901), depository institutions may meet community reinvestment goals by directly originating or purchasing mortgage loans provided to LMI consumers. *See* 12 CFR 228.22.

tightened mortgage loan underwriting requirements in response to uncertainty over the magnitude of potential losses due to delinquencies, defaults, and foreclosures.[48] This restriction in credit availability coincided with increasing unemployment, falling home values, and the onset of subprime ARM resets. As a result, many subprime ARM consumers could not afford their mortgage payments and were not able to obtain refinancings. This led to increases in delinquencies and foreclosures, which prompted further tightening of underwriting standards. Other subprime ARM consumers were able to remain current, but were not able to refinance because of a decrease in their loan-to-value ratio or an increase in their debt-to-income ratio.[49] However, these consumers devoted most of their disposable income to mortgage payments, thereby lowering overall consumer demand and further weakening the national economy.[50]

Policymakers became concerned that the losses incurred from foreclosures on subprime mortgage loans would destabilize the entire mortgage market.[51] There was a particular concern that the uncertainty surrounding exposure to these losses would lead to a fear-induced downward economic spiral.[52] As the crisis worsened, industry stakeholders attempted to stop this self-reinforcing cycle through a series of measures intended to stabilize homeownership and prevent foreclosure. Beginning in late 2008, the Federal government, Federal agencies, and GSEs implemented programs designed to facilitate refinancings and loan modifications.

The Troubled Asset Relief Program. The U.S. government enacted and implemented several programs intended to promote economic recovery by stabilizing homeownership and preventing foreclosure. The Emergency Economic Stabilization Act of 2008,[53] as amended by the American Recovery and Reinvestment Act of 2009,[54] authorizes the Treasury Department to ''use loan guarantees and credit enhancements to facilitate loan modifications to prevent avoidable foreclosures.'' [55] Pursuant to this authority, the Treasury Department established the Troubled Asset Relief Program (TARP), under which two programs were created to provide financial assistance directly to homeowners in danger of losing their homes: the Making Home Affordable (MHA) program and the Hardest Hit Fund (HHF) program. The MHA program is operated by the Treasury Department and seeks to provide Federally-directed assistance to consumers who are at risk of default, foreclosure, or were otherwise harmed by the financial crisis.[56] The HHF program provides funds to certain HFAs in States where the Treasury Department has determined that locally-directed stabilization programs are required.[57]

MHA began with the introduction of the Home Affordable Modification Program (HAMP) in March 2009.[58] HAMP is intended to assist employed homeowners by replacing the consumer's current mortgage loan with a more affordable mortgage loan.[59] HAMP produced nearly 500,000 trial modifications during the first six months of the program.[60] MHA offerings expanded with the creation of the Second Lien Modification Program in August 2009 and the Home Affordable Foreclosure Alternatives Program in November 2009.[61] The Treasury Department subsequently modified these programs several times in response to the changing needs of distressed consumers and the mortgage market.[62]

MHA programs are currently scheduled to expire on December 31, 2013, although there is continuing debate about whether to extend them.[63] As of December 2012, ten programs have been established under MHA. The Treasury Department operates five MHA programs.[64] The remaining five MHA programs are operated in conjunction with U.S. Department of Veterans Affairs (VA), FHA, or USDA programs.[65] Many consumers facing default or foreclosure have received assistance under these programs. For example, from the beginning of the HAMP program to March 2013, over 1.1 million permanent HAMP modifications have been completed, saving distressed consumers an estimated $19.1 billion.[66]

[48] A 2011 OCC survey shows that 56 percent of supervised banks participating in the survey tightened residential real estate underwriting requirements between 2007 and 2008, and 73 percent tightened underwriting requirements between 2008 and 2009. *See* Office of the Comptroller of the Currency, *Survey of Credit Underwriting Practices 2011,* p. 11.

[49] ''[W]ith house prices becoming flat or declining in many parts of the country during 2007, it has become increasingly difficult for many subprime ARM borrowers to refinance. While many such borrowers remain current on their loans or are still able to refinance at market rates or into FHA products, an increasing number have either fallen behind on their existing payments or face the prospect of falling behind when rates reset and they are unable to refinance.'' *Accelerating Loan Modifications, Improving Foreclosure Prevention and Enhancing Enforcement,* 110th Cong. (Dec. 6, 2007) (testimony of John C. Dugan, Comptroller, Office of the Comptroller of the Currency).

[50] By the third quarter of 2007, the ratio of mortgage-related financial obligations (which is comprised of mortgage debt, homeowners' insurance, and property tax) to disposable personal income reached an all-time high of 11.3 percent. *See http://www.federalreserve.gov/releases/housedebt/.*

[51] ''[A]nalysts are concerned that mortgage foreclosures will climb significantly higher and, along with falling housing prices, overwhelm the ability of mortgage markets to restructure or refinance loans for creditworthy borrowers.'' Congressional Budget Office, Options for Responding to Short-Term Economic Weakness, p. 21 (Jan. 2008).

[52] ''[A] breakdown of mortgage markets could put the economy on a self-reinforcing downward spiral of less lending, weaker economic activity, lower house prices, more foreclosures, even less lending, and so on, either causing or significantly worsening a recession.'' *Id.* pp. 21–22.

[53] 12 U.S.C. 5201 *et. seq.;* Public Law 110–343 (Oct. 3, 2008).

[54] *See* Sec. 7002 of Public Law 111–5 (Jan. 6, 2009).

[55] 12 U.S.C. 5219(a)(1).

[56] *See www.makinghomeaffordable.gov.*

[57] *See http://www.treasury.gov/initiatives/financial-stability/TARP-Programs/housing/hhf/Pages/default.aspx.*

[58] *See* Press Release, Treasury Department, *Relief for Responsible Homeowners* (Mar. 4, 2009), *available at: http://www.treasury.gov/press-center/press-releases/Pages/200934145912322.aspx.*

[59] Generally speaking, a loan can be modified under HAMP only if it yields a positive net present value using series of tests involving ''waterfalls.'' Under the waterfall method, servicers must repeatedly project amortizations based on sequential decreases in the interest rate and, if necessary, principal forgiveness, until arriving at a potential loan modification with a target front-end DTI ratio of 31 percent. *See* United States Department of the Treasury, ''Home Affordable Modification Program, Base Net Present Value (NPV) Model v5.02, Model Documentation'' (April 1, 2012), *available at: https://www.hmpadmin.com/portal/programs/docs/hamp_servicer/npvmodeldocumentationv502.pdf. See also* Consumer Compliance Outlook, Federal Reserve Bank of Philadelphia (Third Quarter 2009), *available at: http://www.philadelphiafed.org/bank-resources/publications/consumer-compliance-outlook/2009/third-quarter/q3_02.cfm.*

[60] *See* Troubled Asset Relief Program (TARP) Monthly Report to Congress—September 2009.

[61] *See* United States Department of the Treasury Office of Financial Stability, ''Troubled Asset Relief Program: Two Year Retrospective'' (Oct. 2010).

[62] *See e.g.,* Supplemental Directive 10–02 (Mar. 24, 2010), modifying HAMP, Supplemental Directive 11–07 (July 25, 2011), expanding eligibility for the Home Affordable Unemployment Program, and Supplemental Directive 12–02 (Mar. 9, 2012), expanding HAMP eligibility.

[63] Press Release, Treasury Department, *Expanding our Efforts to Help More Homeowners and Strengthen Hard-hit Communities* (Jan. 27, 2012), *available at: http://www.treasury.gov/connect/blog/Pages/Expanding-our-efforts-to-help-more-homeowners-and-strengthen-hard-hit-communities.aspx.*

[64] In addition to HAMP, the Second Lien Modification Program, and the Home Affordable Foreclosure Alternatives Program, the Treasury Department also operates the Principal Reduction Alternative Program and the Home Affordable Unemployment Program.

[65] These programs are the FHA Home Affordable Modification Program, USDA Special Loan Servicing, Veterans Affairs Home Affordable Modification, FHA Second Lien Modification Program, and the FHA Short Refinance Program.

[66] *See* March 2013 Making Home Affordable Program Performance Report.

In March 2010 the Treasury Department established the HHF program to enable the States most affected by the financial crisis to develop innovative assistance programs.[67] Nineteen programs have been established under the HHF fund, which is currently scheduled to expire on December 31, 2017. These programs provide assistance to homeowners in the District of Columbia and the 18 States most affected by the economic crisis.[68] The HHF provides funds directly to HFAs in these States, which are used to create foreclosure-avoidance programs. As of April 2013, approximately $2.2 billion has been allocated to support the 63 programs established to assist distressed consumers in these localities.[69] In California alone, nearly 17,000 consumers have received over $166 million in assistance since the beginning of the program.[70]

As with the MHA programs discussed above, these HHF programs have evolved over time. The Treasury Department originally encouraged HFAs to establish programs for mortgage modifications, principal forbearance, short sales, principal reduction for consumers with high loan-to-value ratios, unemployment assistance, and second-lien mortgage loan reduction or modification.[71] No HFAs were able to establish all of these programs in the early stages of the HHF. However, through 2011 and 2012 State HHF programs were significantly modified and expanded.[72] The 19 HFAs continue to modify these programs to develop more effective and efficient methods of providing assistance to at-risk consumers. For example, in September 2012 the Nevada HHF program was amended for the tenth time.[73]

Federal agency programs. In response to the financial crisis, the FHA, the VA, and the USDA expanded existing programs and implemented new programs intended to facilitate refinancings for consumers at risk of delinquency or default. Some of these programs operate in conjunction with the Treasury Department's MHA program, while others are run solely by the particular Federal agency. In 2008 Congress expanded access to refinancings under the VA's Interest Rate Reduction Refinancing Loan program by raising the maximum loan-to-value ratio to 100 percent and increasing the maximum loan amount of loans eligible to be guaranteed under the program.[74] In February 2009 HUD increased the maximum loan amount for FHA-insured mortgages.[75] This change expanded access to refinancings available under the FHA's Streamline Refinance Program.[76] Several months later, the FHA created the Short Refinance Option program to assist consumers with non-FHA mortgage loans.[77] This program, which operates in conjunction with TARP, permits underwater consumers to refinance if the current creditor agrees to write down 10 percent of the outstanding principal balance. Similarly, in August 2010 the Rural Housing Service of the USDA (RHS) adopted rules intended to facilitate loan modifications for consumers struggling to make payments on USDA Guaranteed Loans.[78] The USDA subsequently created the Single Family Housing Guaranteed Rural Refinance Pilot Program, which was intended to refinance USDA borrowers into more stable and affordable mortgage loans.[79]

These efforts have enabled many consumers to receive refinancings under these programs. In 2011, the FHA accounted for 5.6 percent of the mortgage refinance market, with originations totaling $59 billion.[80] However, the number of consumers receiving assistance under these programs varies. For example, between April 2009 and December 2011, the FHA started 5.6 million mortgage loan modifications.[81] During a similar time period, nearly 997,000 FHA Streamline Refinances were consummated.[82] In contrast, between February 2010 and September 2012, only 1,772 mortgage loans were refinanced under the Short Refinance Option program.[83] Efforts continue to develop and enhance these programs to assist distressed homeowners while improving the performance of existing mortgage loans owned, insured, or guaranteed by these agencies.

HARP and other GSE refinancing programs. After the GSEs were placed into conservatorship in late 2008, the Federal Housing Finance Agency (FHFA) took immediate steps to reduce GSE losses by mitigating foreclosures.[84] In November 2008 FHFA and the GSEs, in coordination with the Treasury Department and other stakeholders, announced the Streamlined Modification Program, which was intended to help delinquent consumers avoid foreclosure by affordably restructuring mortgage payments.[85] This program was the precursor to the Home Affordable Refinance Program (HARP)

[67] *See* Hardest Hit Fund Program Guidelines Round 1, *available at: http://www.treasury.gov/initiatives/financial-stability/TARP-Programs/housing/Documents/HFA_Proposal_Guidelines_-_1st_Rd.pdf.*

[68] The HHF provides funds to HFAs located in Alabama, Arizona, California, Florida, Georgia, Illinois, Indiana, Kentucky, Michigan, Mississippi, Nevada, New Jersey, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Tennessee, and Washington, DC

[69] *See* Troubled Asset Relief Program (TARP) Monthly Report to Congress—April 2013.

[70] *See* Keep Your Home California 2012 Fourth Quarterly Report.

[71] *See* Hardest Hit Fund Program Guidelines Round 1, *available at: http://www.treasury.gov/initiatives/financial-stability/TARP-Programs/housing/Documents/HFA_Proposal_Guidelines_-_1st_Rd.pdf.*

[72] From 2011–2012, the program agreements between the 19 HFAs and the Treasury Department were modified 55 times. *See http://www.treasury.gov/initiatives/financial-stability/TARP-Programs/housing/hhf/Pages/Archival-information.aspx.*

[73] *See* Tenth Amendment to Commitment to Purchase Financial Instrument and HFA Participation Agreement, *available at: http://www.treasury.gov/initiatives/financial-stability/TARP-Programs/housing/Pages/Program-Documents.aspx.*

[74] *See* Sec. 504 of the Veterans' Benefits Improvement Act of 2008, Public Law 110–389 (Oct. 10, 2008).

[75] *See* HUD Mortgagee Letter 2009–07. Section 1202(b) of the American Recovery and Reinvestment Act of 2009, Public Law 111–5 (Jan. 6, 2009), authorized the Secretary of Housing and Urban Development to increase the loan limit.

[76] The FHA Streamline Refinance Program contains reduced underwriting requirements for consumers with FHA mortgage loans seeking to refinance into a new FHA mortgage loan with a reduced interest rate. The FHA has offered streamline refinances for over thirty years. *See* HUD Mortgagee Letter 1982–23.

[77] *See* HUD Mortgagee Letter 2010–23.

[78] *See* 75 FR 52429 (Aug. 26, 2010).

[79] *See* Rural Dev. Admin. Notice No. 4615 (1980–D) (Feb. 1, 2012).

[80] This number represents FHA's market share by dollar volume. By number of originations, the FHA controlled 6.5 percent of the refinance market, with 312,385 refinances originated. *See* FHA-Insured Single-Family Mortgage Originations and Market Share Report 2012—Q2, *available at: http://portal.hud.gov/hudportal/documents/huddoc?id=fhamktq2_2012.pdf.*

[81] *See* Hearing on FY13 Federal Housing Administration's Budget Request, 112th Cong. (Mar. 8, 2012) (testimony of Carol Galante, Acting Assistant Secretary for Housing/Federal Housing Administration Commissioner for the U.S. Department of Housing and Urban Development).

[82] A total of 996,871 mortgage loans were endorsed under the FHA Streamline Refinance program from Fiscal Year 2009 through 2012. *See* FHA Outlook Reports for Fiscal Years 2009, 2010, 2011, and 2012, *available at: http://portal.hud.gov/hudportal/HUD?src=/program_offices/housing/rmra/oe/rpts/ooe/olmenu.*

[83] *See* Office of the Special Inspector General for the Troubled Asset Relief Program, Quarterly Report to Congress, p. 64 (Oct. 25, 2012).

[84] *See* Press Release, FHFA, *Statement of FHFA Director James B. Lockhart* (Sept. 7, 2008), *available at: http://www.fhfa.gov/webfiles/23/FHFAStatement9708final.pdf.*

[85] *See* Press Release, FHFA, *FHFA Announces Implementation Plans for Streamlined Loan Modification Program,* (Dec. 18, 2008), *available at: http://www.fhfa.gov/webfiles/267/SMP implementation121808.pdf.*

that was announced in March 2009.[86] The HARP program was originally set to expire in June 2010 and limited to consumers with a loan-to-value ratio that did not exceed 105 percent. However, HARP was modified over time to account for the deteriorating mortgage market. In July 2010 the maximum loan-to-value ratio was increased from 105 percent to 125 percent.[87] Nine months later FHFA extended the HARP expiration date by one year, to June 30, 2011.[88]

Many of the nearly five million eligible consumers were expected to receive refinancings under HARP.[89] However, by mid-2011 fewer than one million consumers had received HARP refinances. Fannie Mae, Freddie Mac, and FHFA responded by significantly altering the HARP program.[90] Perhaps most significantly, the maximum loan-to-value ratio was removed, facilitating refinances for all underwater consumers who otherwise fit HARP's criteria. More HARP refinances were completed during the first six months of 2012 than in all of 2011.[91] These changes were especially effective in assisting consumers with high loan-to-value ratios. In September 2012, consumers with loan-to-value ratios in excess of 125 percent received 26 percent of all HARP refinances.[92]

The GSEs have implemented other streamline refinance programs intended to facilitate the refinancing of existing GSE consumers into more affordable mortgage loans. These programs are available for consumers who are not eligible for a refinancing under HARP. For example, a consumer with a loan-to-value ratio of less than 80 percent is eligible for a streamline refinancing through Fannie Mae's Refi Plus program or Freddie Mac's Relief Refinance program. These programs comprise a significant share of GSE refinancing activity. From January through September 2012, 45 percent of GSE streamline refinances were non-HARP refinances.[93] FHFA and the GSEs remain committed to continue modifying these programs to enhance access to refinancing credit for distressed consumers.[94] In April 2013, FHFA extended the HARP expiration date to December 31, 2015.[95]

The Mortgage Loan Market for Small Portfolio Creditors

Traditionally, underwriting standards were determined at the branch or local bank level. These practices heavily emphasized the relationship between the bank and the consumer.[96] Starting in the mid-1990s, much of the mortgage market began to move toward standardized underwriting practices based on quantifiable and verifiable data points, such as a consumer's credit score.[97] The shift toward standardized, electronic underwriting lowered costs for creditors and consumers, thereby increasing access to mortgage credit. Standardized loan-level data made it easier to analyze individual loans for compliance with underwriting requirements, which facilitated the expansion of private mortgage securitizations. This shift from portfolio-focused to securitization-focused mortgage lending also altered the traditional risk calculations undertaken by creditors, as creditors no longer retained the risks associated with poorly underwritten loans.[98] Additionally, in another departure from the traditional mortgage lending model, these creditors increasingly relied on the fees earned by originating and selling mortgage loans, as opposed to the interest revenue derived from the loan itself.

Small community creditor access to the secondary mortgage market was limited. Many small creditors originated ''non-conforming'' loans which could not be purchased by the GSEs. Also, many community creditors chose to retain the relationship model of underwriting, rather than fully adopting standardized data models popular with larger banks. Retaining these traditional business methods had important consequences during the subprime crisis. While large lending institutions generally depended on the secondary market for funding, small community banks and credit unions generally remained reliant on deposits to fund mortgage loans held in portfolio. As a result, community creditors were less affected by the contraction in the secondary mortgage market during the financial crisis.[99] For example, the percentage of mortgage-backed securities in relation to the total assets of credit unions actually declined by more than 1.5 percent as subprime lending expanded.[100]

Furthermore, by retaining mortgage loans in portfolio community creditors also retain the risk of delinquency or default on those loans. The presence of portfolio lending within this market remains an important influence on the underwriting practices of community banks and credit unions. These institutions generally rely on long-term relationships with a small group of consumers. Therefore, the reputation of these community banks and credit unions is largely dependent on serving their community in ways that cause no harm. Thus, community creditors have an added incentive to engage in thorough underwriting to protect their balance sheet as well as their reputation. To minimize portfolio performance risk, small community creditors have developed underwriting standards that are different than those employed by larger institutions. Small creditors generally engage in ''relationship banking,'' in which underwriting decisions rely on qualitative

[86] *See* Press Release, Treasury Department, *Relief for Responsible Homeowners* (Mar. 4, 2009), *available at: http://www.treasury.gov/press-center/press-releases/Pages/200934145912322.aspx.*

[87] *See* Press Release, FHFA, *FHFA Authorized Fannie Mae and Freddie Mac to Expand Home Affordable Refinance Program to 125 Percent Loan-to-Value* (July 1, 2009), *available at: http://www.fhfa.gov/webfiles/13495/125_LTV_release_and_fact_sheet_7_01_09%5B1%5D.pdf.*

[88] *See* Press Release, FHFA, *FHFA Extends Refinance Program By One Year* (Mar. 1, 2010), *available at: http://www.fhfa.gov/webfiles/15466/HARPEXTENDED3110%5B1%5D.pdf.*

[89] *See* Treasury Department Press Release *supra* note 94.

[90] *See* Press Release, FHFA, *FHFA, Fannie Mae and Freddie Mac Announce HARP Changes to Reach More Borrowers* (Oct. 24, 2011), *available at: http://www.fhfa.gov/webfiles/22721/HARP_release_102411_Final.pdf.*

[91] *See* Federal Housing Finance Agency Refinance Report (June 2012).

[92] *See* Federal Housing Finance Agency Refinance Report (Sept. 2012).

[93] *Id.*

[94] ''Today, we continue to meet with lenders to ensure HARP is helping underwater borrowers refinance at today's historical low interest rates. As we continue to gain insight from the program we will make additional operational adjustments as needed to enhance access to this program.'' Edward J. DeMarco, Acting Director Federal Housing Finance Agency, Remarks at the American Mortgage Conference (Sept. 10, 2012), *available at: http://www.fhfa.gov/webfiles/24365/2012DeMarcoNCSpeechFinal.pdf.*

[95] *See* Press Release, FHFA, *FHFA Extends HARP to 2015* (Apr. 11, 2013), *available at: http://www.fhfa.gov/webfiles/22721/HARP_release_102411_Final.pdf.*

[96] ''[C]ommunity banks tend to base credit decisions on local knowledge and nonstandard data obtained through long-term relationships and are less likely to rely on the models-based underwriting used by larger banks.'' Federal Deposit Insurance Corporation, *FDIC Community Banking Study,* p. 1–1 (Dec. 2012) (FDIC Community Banking Study).

[97] *See FCIC Report* at 72.

[98] *See FCIC Report* at 89.

[99] Between 2005 and 2008, while loan originations at banks with assets in excess of $10 billion fell by 51 percent, loan originations at banks with assets between $1 and $10 billion declined by 31 percent, and loan originations at banks with less than $1 billion in assets declined by only 10 percent. *See* Federal Reserve Bank of Kansas City, *Financial Industry Perspectives* (Dec. 2009).

[100] In December 2003, the ratio of mortgage-backed securities to total assets at credit unions was 4.67 percent. By December 2006, this ratio had decreased to 3.21 percent. *See Accelerating Loan Modifications, Improving Foreclosure Prevention and Enhancing Enforcement,* 110th Cong. (Dec. 6, 2007) (testimony of Gigi Hyland, Board Member of the National Credit Union Administration).

information gained from personal relationships between creditors and consumers.[101] This qualitative information, often referred to as ''soft'' information, focuses on subjective factors such as consumer character and reliability, which ''may be difficult to quantify, verify, and communicate through the normal transmission channels of a banking organisation.'' [102] Evidence suggests that underwriting based on such ''soft'' information yields loan portfolios that perform better than those underwritten according to ''hard'' information, such as credit score and consumer income levels.[103] For example, one recent study found that delinquency and default rates were significantly lower for consumers receiving mortgage loans from institutions relying on soft information for underwriting decisions.[104] This is consistent with market-wide data demonstrating that mortgage loan delinquency and charge-off rates are significantly lower at smaller banks than larger ones.[105] Current data also suggests that that these relationship-based lending practices lead to more accurate underwriting decisions during cycles of both lending expansion and contraction.[106]

Although the number of community banks has declined in recent years, these institutions remain an important source of nonconforming credit and of mortgage credit generally in areas commonly considered ''rural'' or ''underserved.'' The Bureau's estimates based on Home Mortgage Disclosure Act (HMDA) and the Consolidated Report of Condition and Income (Call Report) data suggest that approximately one half of all nonconforming loans are originated by creditors with assets less than $2 billion and approximately one quarter are originated by creditors with total assets less than $2 billion that originate fewer than 500 first-lien mortgages annually. In 2011, community banks held over 50 percent of all deposits in micropolitan areas and over 70 percent of all deposits held in rural areas.[107] Similarly, in 2011, there were more than 600 counties where community banks operated offices but where no noncommunity bank offices were present, and more than 600 additional counties where community banks operated offices but where fewer than three noncommunity bank offices were present.[108] These counties have a combined population of more than 16 million people and include both rural and metropolitan areas.[109] It is important to note that the cost of credit offered by these community institutions is generally higher than the cost of similar products offered by larger institutions. One reason for this increased expense stems from the nature of relationship-based underwriting decisions. Such qualitative evaluations of creditworthiness tend to take more time, and therefore are more expensive, than underwriting decisions based on standardized points of data.[110] Also, the cost of funds for community banks tends to be higher than the cost for larger institutions.[111]

B. Statutory and Regulatory Background

For over 20 years, consumer advocates, legislators, and regulators have raised concerns about creditors originating mortgage loans without regard to the consumer's ability to repay the loan. Beginning in about 2006, these concerns were heightened as mortgage delinquencies and foreclosure rates increased dramatically, caused in part by the gradual deterioration in underwriting standards. *See* 73 FR 44524 (Jul. 30, 2008). For detailed background information, including a summary of the legislative and regulatory responses to this issue, which culminated in the enactment of the Dodd-Frank Act on July 21, 2010, the Board of Governors of the Federal Reserve System's (the Board) issuance of a proposed rule on May 11, 2011 to implement certain amendments to TILA made by the Dodd-Frank Act, and the Bureau's issuance of the 2013 ATR Final Rule, see the discussion in the 2013 ATR Final Rule. *See* 78 FR 6410–6420 (Jan. 30, 2013).

The Bureau's ATR Final Rule

The Bureau's 2013 ATR Final Rule implemented the ability-to-repay requirements under TILA section 129C. Consistent with the statute, the Bureau's 2013 ATR Final Rule adopted § 1026.43(a), which applies the ability-to-repay requirements to any consumer credit transaction secured by a dwelling, except an open-end credit plan, timeshare plan, reverse mortgage, or temporary loan.

As adopted, § 1026.43(c) provides that a creditor is prohibited from making a covered mortgage loan unless the creditor makes a reasonable and good faith determination, based on verified and documented information, that the consumer will have a reasonable ability to repay the loan, including any mortgage-related obligations (such as property taxes and mortgage insurance). Section 1026.43(c) describes certain requirements for making ability-to-repay determinations, but does not provide comprehensive underwriting standards to which creditors must adhere. At a minimum, however, the creditor must consider and verify eight underwriting factors: (1) Current or reasonably expected income or assets; (2) current employment status; (3) the monthly

[101] ''Many customers . . . value the intimate knowledge their banker has of their business and/or total relationship and prefer dealing consistently with the same individuals whom they do not have to frequently reeducate about their own unique financial and business situations. Such customers are consequently willing to pay relatively more for such service. Relationship lending thus provides a niche for community institutions that many large banks find less attractive or are less capable of providing.'' *See* Federal Reserve Bank of Atlanta, *On the Uniqueness of Community Banks* (Oct. 2005).

[102] *See* Allen N. Berger and Gregory F. Udell, *Small Business Credit Availability and Relationship Lending: The Importance of Bank Organisational Structure,* Economic Journal (2002).

[103] ''Moreover, a comparison of loss rates on individual loan categories suggests that community banks may also do a better job of underwriting loans than noncommunity institutions (see Table 4.4).'' *FDIC Community Banking Study,* p. 4–6. *See also* Sumit Agarwal, Brent W. Ambrose, Souphala Chomsisengphet, and Chunlin Liu, *The Role of Soft Information in a Dynamic Contract Setting: Evidence from the Home Equity Market,* 43 Journal of Money, Credit and Banking 633, 649 (Oct. 2011) (analyzing home equity lending, the authors ''find that the lender's use of soft information can successfully reduce the risks associated with *ex post* credit losses.'').

[104] ''In particular, we find evidence that selection and soft information prior to purchase are significantly associated with reduced delinquency and default. And, in line with relationship lending, we find that this effect is most pronounced for borrowers with compromised credit (credit scores below 660), who likely benefit the most from soft information in the lending relationship. This suggests that for higher risk borrowers, relationship with a bank may be about more than the mortgage transaction.'' O. Emre Ergungor and Stephanie Moulton, *Beyond the Transaction: Depository Institutions and Reduced Mortgage Default for Low-Income Homebuyers,* Federal Reserve Bank of Cleveland Working Paper 11–15 (Aug. 2011).

[105] Federal Reserve Board, *Charge-Off and Delinquency Rates on Loans and Leases at Commercial Banks* (Nov. 2012), *available at: http://www.federalreserve.gov/releases/chargeoff/default.htm.* These data show that residential real estate charge-offs were higher at large banks than small ones for 12 of the previous 87 quarters, dating to the start of the small bank survey in 1991. For example, in the fourth quarter of 2009 large banks had a 3.16 percent charge-off rate, while the rate at small banks was 1.2 percent. Delinquency rates demonstrate a similar effect.

[106] ''In two retail loan categories—residential real estate loans and loans to individuals—community banks consistently reported lower average loss rates from 1991 through 2011, the period for which these data are available.'' *FDIC Community Banking Study,* p. 4–6.

[107] *FDIC Community Banking Study,* p. 3–6.

[108] *FDIC Community Banking Study,* p. 3–5.

[109] *Id.*

[110] *FCIC Report* at 72.

[111] *FDIC Community Banking Study,* p. 4–5; Government Accountability Office, *Community Banks and Credit Unions: Impact of the Dodd-Frank Act Depends Largely on Future Rulemakings,* p. 10 (Sept. 2012) (GAO Community Banks and Credit Unions Report).

payment on the covered transaction; (4) the monthly payment on any simultaneous loan; (5) the monthly payment for mortgage-related obligations; (6) current debt obligations; (7) the monthly debt-to-income ratio or residual income; and (8) credit history.

Section 1026.43(c)(3) generally requires the creditor to verify the information relied on in determining a consumer's repayment ability using reasonably reliable third-party records, with special rules for verifying a consumer's income or assets. Section 1026.43(c)(5)(i) requires the creditor to calculate the monthly mortgage payment based on the greater of the fully indexed rate or any introductory rate, assuming monthly, fully amortizing payments that are substantially equal. Section 1026.43(c)(5)(ii) provides special payment calculation rules for loans with balloon payments, interest-only loans, and negative amortization loans.

Section 1026.43(d) provides special rules for complying with the ability-to-repay requirements for a creditor refinancing a ''non-standard mortgage'' into a ''standard mortgage.'' This provision is based on TILA section 129C(a)(6)(E), which contains special rules for the refinancing of a ''hybrid loan'' into a ''standard loan.'' The purpose of this provision is to provide flexibility for creditors to refinance a consumer out of a risky mortgage into a more stable one without undertaking a full underwriting process. Under § 1026.43(d), a non-standard mortgage is defined as an adjustable-rate mortgage with an introductory fixed interest rate for a period of one year or longer, an interest-only loan, or a negative amortization loan. Under this option, a creditor refinancing a non-standard mortgage into a standard mortgage does not have to consider the eight specific underwriting criteria listed under § 1026.43(c), if certain conditions are met.

Section 1026.43(e) specifies requirements for originating ''qualified mortgages,'' as well as standards for when the presumption of compliance with ability-to-repay requirements can be rebutted. Section 1026.43(e)(1)(i) provides a safe harbor under the ability-to-repay requirements for loans that satisfy the definition of a qualified mortgage and are not higher-priced covered transactions (*i.e.,* the APR does not exceed APOR [112] plus 1.5 percentage points for first-lien loans or 3.5 percentage points for subordinate-lien loans). Section 1026.43(e)(1)(ii) provides a rebuttable presumption for qualified mortgage loans that are higher-priced covered transactions (*i.e.,* the APR exceeds APOR plus 1.5 percent for first lien or 3.5 percent for subordinate lien). Under the 2013 ATR Final Rule, § 1026.43 also provides three options for creditors to originate a qualified mortgage:

Qualified mortgage—general. Under the general definition for qualified mortgages in § 1026.43(e)(2), a creditor must satisfy the statutory criteria restricting certain product features and points and fees on the loan, consider and verify certain underwriting requirements that are part of the general ability-to-repay standard, and confirm that the consumer has a total (or ''back-end'') debt-to-income ratio that is less than or equal to 43 percent. To determine whether the consumer meets the specific debt-to-income ratio requirement, the creditor must calculate the consumer's monthly debt-to-income ratio in accordance with appendix Q. A loan that satisfies these criteria and is not a higher-priced covered transaction receives a legal safe harbor from the ability-to-repay requirements. A loan that satisfies these criteria and is a higher-priced covered transaction receives a rebuttable presumption of compliance with the ability-to-repay requirements.

Qualified mortgage—special rules. The second option for originating a qualified mortgage provides a temporary alternative to the general definition in § 1026.43(e)(2). This option is intended to avoid unnecessarily disrupting the mortgage market at a time when it is especially fragile, as a result of the recent mortgage crisis. Section 1026.43(e)(4) provides that a loan is a qualified mortgage if it meets the statutory limitations on product features and points and fees, satisfies certain other requirements, and is eligible for purchase, guarantee, or insurance by one of the following entities:

- Fannie Mae or Freddie Mac, while operating under the conservatorship or receivership of the Federal Housing Finance Agency pursuant to section 1367 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992;
- Any limited-life regulatory entity succeeding the charter of either Fannie Mae or Freddie Mac pursuant to section 1367(i) of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992;
- The U.S. Department of Housing and Urban Development under the National Housing Act (FHA);
- The U.S. Department of Veterans Affairs (VA);
- The U.S. Department of Agriculture (USDA); or
- The U.S. Department of Agriculture Rural Housing Service (RHS).

With respect to GSE-eligible loans, this temporary provision expires when conservatorship of the GSEs ends. With respect to each other category of loan, this provision expires on the effective date of a rule issued by each respective Federal agency pursuant to its authority under TILA section 129C(b)(3)(ii) to define a qualified mortgage. In any event, this temporary provision expires no later than January 10, 2021.

Qualified mortgage—balloon-payment loans by certain creditors. The third option for originating qualified mortgages is included under § 1026.43(f), which provides that a small creditor operating predominantly in rural or underserved areas can originate a balloon-payment qualified mortgage. The Dodd-Frank Act generally prohibits balloon-payment mortgages from being qualified mortgages. However, the statute creates a limited exception, with special underwriting rules, for loans made by a creditor that: (1) Operates predominantly in rural or underserved areas; (2) together with affiliates, has total annual residential mortgage loan originations that do not exceed a limit set by the Bureau; and (3) retains the balloon loans in portfolio. The purpose of this definition is to preserve credit availability in rural or underserved areas by assuring that small creditors offering loans that cannot be sold on the secondary market, and therefore must be placed on the creditor's balance sheet, are able to use a balloon-payment structure as a means of controlling interest rate risk.

Section 1026.43(f)(1)(vi) limits eligibility to creditors that originated 500 or fewer covered transactions secured by a first-lien in the preceding calendar year and that have assets of no more than $2 billion (to be adjusted annually). In addition, to originate a balloon-payment qualified mortgage more than 50 percent of a creditor's total first-lien covered transactions must have been secured by properties in counties that are ''rural'' or ''underserved,'' as designated by the Bureau. A county is ''rural'' if, during a calendar year, it is located in neither a metropolitan statistical area nor a micropolitan statistical area adjacent to a metropolitan statistical area, as those terms are defined by the U.S. Office of Management and Budget. A county is ''underserved'' if no more than two creditors extend covered transactions five or more times in that county during

[112] TILA section 129C(b)(2)(B) defines the average prime offer rate as ''the average prime offer rate for a comparable transaction as of the date on which the interest rate for the transaction is set, as published by the Bureau.'' 15 U.S.C. 1639c(b)(2)B).

a calendar year. Also, except as provided, the balloon-payment qualified mortgage must generally be held in portfolio for at least three years. Balloon loans by such creditors are eligible for qualified mortgage status if they meet the statutory limitations on product features and points and fees, and if the creditor follows certain other requirements that are part of the general ability-to-repay standard.

The Bureau's 2013 ATR Final Rule added two additional requirements to § 1026.43. Section 1026.43(g) implements the Dodd-Frank Act limits on prepayment penalties. Section 1026.43(h) prohibits a creditor from structuring a closed-end extension of credit as an open-end plan to evade the ability-to-repay requirements.

III. Summary of the Rulemaking Process

A. The Bureau's Proposal

As discussed above, TILA section 129C, as added by sections 1411, 1412, and 1414 of the Dodd-Frank Act, generally requires creditors to make a reasonable, good faith determination of a consumer's ability to repay the loan. On January 10, 2013, the Bureau issued the 2013 ATR Final Rule to implement these ability-to-repay requirements. *See* 78 FR 6407 (Jan. 30, 2013). At the same time, the Bureau issued the 2013 ATR Proposed Rule related to certain proposed exemptions, modifications, and clarifications to the ability-to-repay requirements and qualified mortgage provisions. *See* 78 FR 6621 (Jan. 30, 2013). The 2013 ATR Proposed Rule contained three major elements.

First, the Bureau proposed certain exemptions from the ability-to-repay requirements for housing finance agencies, certain nonprofit creditors, certain homeownership stabilization and foreclosure prevention programs, and certain Federal agency and GSE refinancing programs. The Bureau was concerned that the ability-to-repay requirements were substantially different from the underwriting requirements employed by these creditors or required under these programs, which would discourage participation in and frustrate the purposes of these programs and significantly impair access to responsible, affordable credit for certain consumers.

Second, the Bureau proposed modifications related to certain small creditors. Specifically, the Bureau proposed an additional definition of a qualified mortgage for certain loans made and held in portfolio by small creditors. The proposed new category would include certain loans originated by small creditors [113] that: (1) Have total assets of $2 billion or less at the end of the previous calendar year; and (2) together with all affiliates, originated 500 or fewer first-lien covered transactions during the previous calendar year. The proposed new category would include only loans held in portfolio by these creditors. The loans also would have to conform to all of the requirements under the general definition of a qualified mortgage except the 43 percent limit on monthly debt-to-income ratio. The Bureau also proposed to allow small creditors and small creditors operating predominantly in rural and underserved areas to charge a higher annual percentage rate for first-lien qualified mortgages in the proposed new category and still benefit from a conclusive presumption of compliance or ''safe harbor.'' A qualified mortgage in the proposed new category would be conclusively presumed to comply if the annual percentage rate is equal to or less than APOR plus 3.5 percentage points for both first-lien and subordinate-lien loans. The Bureau also posed and solicited comment on a specific question regarding whether there is a need for transition mechanisms for existing balloon loans that may end soon after the new rule takes effect.

Finally, the Bureau proposed several additional interpretive comments concerning the inclusion of loan originator compensation in the points and fees calculation under the qualified mortgage provisions and the high-cost mortgage provisions under HOEPA. The proposed comments addressed situations in which payments flow from one party to another over the course of a mortgage transaction and whether to count compensation separately where it may already have been counted toward points and fees under another element of the regulatory definition. In addition, the Bureau sought feedback on whether additional clarification was warranted in light of the Bureau's separate rulemaking to implement provisions of the Dodd-Frank Act restricting certain loan originator compensation practices.

B. Comments and Post-Proposal Outreach

In response to the proposed rule, the Bureau received approximately 1,150 letters from commenters, including members of Congress, creditors, consumer groups, trade associations, mortgage and real estate market participants, and individual consumers. The comments focused on all aspects of the proposal, including:

- the calculation of loan originator compensation for inclusion in points and fees for the qualified mortgage and high-cost mortgage points and fees limits;
- the proposed exemptions from the ability-to-repay requirements for housing finance agencies, certain nonprofit creditors, certain homeownership stabilization and foreclosure prevention programs, and certain Federal agency and GSE refinancing programs;
- the proposed definition of a fourth category of qualified mortgages including loans originated and held in portfolio by certain small creditors; and
- the proposed amendments to the definition of higher-priced covered transaction with respect to qualified mortgages that are originated and held in portfolio by small creditors and with respect to balloon-payment qualified mortgages originated and held in portfolio by small creditors operating predominantly in rural or underserved areas.

Materials submitted were filed in the record and are publicly available at *http://www.regulations.gov.* The Bureau also elected to consider the comments received after the expiration of the comment period. As discussed in more detail below, the Bureau has considered these comments in adopting this final rule.

IV. Legal Authority

The Bureau is issuing this final rule pursuant to its authority under TILA and the Dodd-Frank Act. *See* 15 U.S.C. 1604(a), 12 U.S.C. 5512(b)(1).

A. TILA Ability-to-Repay and Qualified Mortgage Provisions

As discussed above, the Dodd-Frank Act amended TILA to provide that, in accordance with regulations prescribed by the Bureau, no creditor may make a residential mortgage loan unless the creditor makes a reasonable and good faith determination based on verified and documented information that, at the time the loan is consummated, the consumer has a reasonable ability to repay the loan, according to its terms, and all applicable taxes, insurance (including mortgage guarantee insurance), and assessments. TILA section 129C(a)(1); 15 U.S.C. 1639c(a)(1). As described below in part IV.B, the Bureau has authority to prescribe regulations to carry out the

[113] The $2 billion threshold reflects the purposes of the proposed category and the structure of the mortgage lending industry. The Bureau's choice of $2 billion in assets as a threshold for purposes of TILA section 129C does not imply that a threshold of that type or of that magnitude would be an appropriate way to distinguish small firms for other purposes or in other industries.

purposes of TILA pursuant to TILA section 105(a). 15 U.S.C. 1604(a). In particular, it is the purpose of TILA section 129C, as amended by the Dodd-Frank Act, to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans and that are understandable and not unfair, deceptive, or abusive. TILA section 129B(a)(2); 15 U.S.C. 1639b(a)(2).

TILA, as amended by the Dodd-Frank Act, also provides creditors originating ''qualified mortgages'' special protection from liability under the ability-to-repay requirements. TILA section 129C(b), 15 U.S.C. 1639c(b). TILA generally defines a ''qualified mortgage'' as a residential mortgage loan for which: the loan does not contain negative amortization, interest-only payments, or balloon payments; the term does not exceed 30 years; the points and fees generally do not exceed 3 percent of the loan amount; the income or assets are considered and verified; and the underwriting is based on the maximum rate during the first five years, uses a payment schedule that fully amortizes the loan over the loan term, and takes into account all mortgage-related obligations. TILA section 129C(b)(2), 15 U.S.C. 1639c(b)(2). In addition, to constitute a qualified mortgage a loan must meet ''any guidelines or regulations established by the Bureau relating to ratios of total monthly debt to monthly income or alternative measures of ability to pay regular expenses after payment of total monthly debt, taking into account the income levels of the borrower and such other factors as the Bureau may determine are relevant and consistent with the purposes described in [TILA section 129C(b)(3)(B)(i)].''

TILA, as amended by the Dodd-Frank Act, also provides the Bureau with authority to prescribe regulations that revise, add to, or subtract from the criteria that define a qualified mortgage upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of the ability-to-repay requirements; or are necessary and appropriate to effectuate the purposes of the ability-to-repay requirements, to prevent circumvention or evasion thereof, or to facilitate compliance with TILA sections 129B and 129C. TILA section 129C(b)(3)(B)(i), 15 U.S.C. 1639c(b)(3)(B)(i). In addition, TILA section 129C(b)(3)(A) provides the Bureau with authority to prescribe regulations to carry out the purposes of the qualified mortgage provisions—to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C. TILA section 129C(b)(3)(A), 15 U.S.C. 1939c(b)(3)(A). As discussed in the section-by-section analysis below, the Bureau is issuing certain provisions of this rule pursuant to its authority under TILA section 129C(b)(3)(B)(i).

In addition, for purposes of defining ''qualified mortgage,'' TILA section 129C(b)(2)(A)(vi) provides the Bureau with authority to establish guidelines or regulations relating to monthly debt-to-income ratios or alternative measures of ability to repay. As discussed in the section-by-section analysis below, the Bureau is issuing certain provisions of this rule pursuant to its authority under TILA sections 129C(b)(2)(A)(vi).

B. Other Rulemaking and Exception Authorities

This final rule also relies on the rulemaking and exception authorities specifically granted to the Bureau by TILA and the Dodd-Frank Act, including the authorities discussed below.

TILA

TILA section 105(a). As amended by the Dodd-Frank Act, TILA section 105(a), 15 U.S.C. 1604(a), directs the Bureau to prescribe regulations to carry out the purposes of TILA, and provides that such regulations may contain additional requirements, classifications, differentiations, or other provisions, and may provide for such adjustments and exceptions for all or any class of transactions, that the Bureau judges are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance therewith. A purpose of TILA is ''to assure a meaningful disclosure of credit terms so that the consumer will be able to compare more readily the various credit terms available to him and avoid the uninformed use of credit.'' TILA section 102(a), 15 U.S.C. 1601(a). This stated purpose is informed by Congress's finding that ''economic stabilization would be enhanced and the competition among the various financial institutions and other firms engaged in the extension of consumer credit would be strengthened by the informed use of credit[.]'' TILA section 102(a). Thus, strengthened competition among financial institutions is a goal of TILA, achieved through the effectuation of TILA's purposes.

As amended by section 1402 of the Dodd-Frank Act, section 129B(a)(2) of TILA provides that a purpose of section 129C of TILA is ''to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans.'' This stated purpose is informed by Congress's finding that ''economic stabilization would be enhanced by the protection, limitation, and regulation of the terms of residential mortgage credit and the practices related to such credit, while ensuring that responsible, affordable mortgage credit remains available to consumers.'' Thus, ensuring that responsible, affordable mortgage credit remains available to consumers is a goal of TILA, achieved through the effectuation of TILA's purposes.

Historically, TILA section 105(a) has served as a broad source of authority for rules that promote the informed use of credit through required disclosures and substantive regulation of certain practices. However, Dodd-Frank Act section 1100A clarified the Bureau's section 105(a) authority by amending that section to provide express authority to prescribe regulations that contain ''additional requirements'' that the Bureau finds are necessary or proper to effectuate the purposes of TILA, to prevent circumvention or evasion thereof, or to facilitate compliance. This amendment clarified the authority to exercise TILA section 105(a) to prescribe requirements beyond those specifically listed in the statute that meet the standards outlined in section 105(a). The Dodd-Frank Act also clarified the Bureau's rulemaking authority over certain high-cost mortgages pursuant to section 105(a). As amended by the Dodd-Frank Act, TILA section 105(a) authority to make adjustments and exceptions to the requirements of TILA applies to all transactions subject to TILA, except with respect to the provisions of TILA section 129, 15 U.S.C. 1639, that apply to the high-cost mortgages defined in TILA section 103(bb), 15 U.S.C. 1602(bb).

As discussed in the section-by-section analysis below, the Bureau is issuing regulations to carry out TILA's purposes, including such additional requirements, adjustments, and exceptions as, in the Bureau's judgment, are necessary and proper to carry out the purposes of TILA, prevent circumvention or evasion thereof, or to facilitate compliance. In developing these aspects of the final rule pursuant to its authority under TILA section 105(a), the Bureau has considered the purposes of TILA, including ensuring that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans, ensuring meaningful

disclosures, facilitating consumers' ability to compare credit terms, and helping consumers avoid the uninformed use of credit, and the findings of TILA, including regulating the terms of residential mortgage credit and the practices related to such credit to ensure that responsible, affordable mortgage credit remains available to consumers, strengthening competition among financial institutions, and promoting economic stabilization.

TILA section 105(f). Section 105(f) of TILA, 15 U.S.C. 1604(f), authorizes the Bureau to exempt from all or part of TILA all or any class of transactions (other than transactions involving any mortgage described in TILA section 103(aa), which are high-cost mortgages) if the Bureau determines that TILA coverage does not provide a meaningful benefit to consumers in the form of useful information or protection. In exercising this authority, the Bureau must consider the factors identified in section 105(f) of TILA and publish its rationale at the time it proposes an exemption for public comment. Specifically, the Bureau must consider:

(a) The amount of the loan and whether the disclosures, right of rescission, and other provisions provide a benefit to the consumers who are parties to such transactions, as determined by the Bureau;

(b) The extent to which the requirements of TILA complicate, hinder, or make more expensive the credit process for the class of transactions;

(c) The status of the borrower, including—

(1) Any related financial arrangements of the borrower, as determined by the Bureau;

(2) The financial sophistication of the borrower relative to the type of transaction; and

(3) The importance to the borrower of the credit, related supporting property, and coverage under TILA, as determined by the Bureau;

(d) Whether the loan is secured by the principal residence of the consumer; and

(e) Whether the goal of consumer protection would be undermined by such an exemption.

As discussed in the section-by-section analysis below, the Bureau is adopting exemptions for certain classes of transactions from the requirements of TILA pursuant to its authority under TILA section 105(f). In determining which classes of transactions to exempt under TILA section 105(f), the Bureau has considered the relevant factors and determined that the exemptions are appropriate.

The Dodd-Frank Act

Dodd-Frank Act section 1022(b). Section 1022(b)(1) of the Dodd-Frank Act authorizes the Bureau to prescribe rules ''as may be necessary or appropriate to enable the Bureau to administer and carry out the purposes and objectives of the Federal consumer financial laws, and to prevent evasions thereof.'' 12 U.S.C. 5512(b)(1). TILA and title X of the Dodd-Frank Act are Federal consumer financial laws. Accordingly, the Bureau is exercising its authority under Dodd-Frank Act section 1022(b) to prescribe rules that carry out the purposes and objectives of TILA and title X and prevent evasion of those laws.

V. Section-by-Section Analysis

Section 1026.32 Requirements for High-Cost Mortgages

32(b) Definitions

32(b)(1)

32(b)(1)(ii)

Background

TILA section 129C(b)(2)(A)(vii), as added by section 1412 of the Dodd-Frank Act, defines a ''qualified mortgage'' as a loan for which, among other things, the total ''points and fees'' payable in connection with the transaction generally do not exceed 3 percent of the total loan amount. Section 1431(a) of the Dodd-Frank Act amended HOEPA's points and fees coverage test to provide in TILA section 103(bb)(1)(A)(ii) that a mortgage is a high-cost mortgage if the total points and fees payable in connection with the transaction exceed 5 percent of the total transaction amount (for transactions of $20,000 or more), or the lesser of 8 percent of the total transaction amount or $1,000 (for transactions of less than $20,000) or other prescribed amount. The Bureau finalized the Dodd-Frank Act's amendments to TILA concerning the points and fees limit for qualified mortgages and the points and fees coverage threshold for high-cost mortgages in the 2013 ATR Final Rule and in the final rule implementing the Dodd-Frank Act's amendments to HOEPA,[114] respectively.

Those rulemakings also adopted the Dodd-Frank Act's amendments to TILA concerning the exclusion of certain bona fide third-party charges and up to two bona fide discount points from the points and fees calculation for both qualified mortgages and high-cost mortgages. With respect to bona fide discount points in particular, TILA sections 129C(b)(2)(C)(ii)(I) and 103(dd)(1) provide for the exclusion of up to and including two bona fide discount points from points and fees for qualified mortgages and high-cost mortgages, respectively, but only if the interest rate for the transaction before the discount does not exceed by more than one percentage point the average prime offer rate, as defined in § 1026.35(a)(2). Similarly, TILA sections 129C(b)(2)(C)(ii)(II) and 103(dd)(2) provide for the exclusion of up to and including one bona fide discount point from points and fees, but only if the interest rate for the transaction before the discount does not exceed the average prime offer rate by more than two percentage points.[115] The Bureau's 2013 ATR and HOEPA Final Rules implemented the bona fide discount point exclusions from points and fees in § 1026.32(b)(1)(i)(E) and (F) (closed-end credit) and (b)(2)(i)(E) and (F) (open-end credit), respectively.

TILA section 129C(b)(2)(C) defines ''points and fees'' for qualified mortgages and high-cost mortgages to have the same meaning as set forth in TILA section 103(aa)(4) (renumbered as section 103(bb)(4)).[116] Points and fees for the high-cost mortgage threshold are defined in § 1026.32(b)(1) (closed-end credit) and (2) (open-end credit), and § 1026.43(b)(9) provides that, for a qualified mortgage, ''points and fees'' has the same meaning as in § 1026.32(b)(1).

Section 1431 of the Dodd-Frank Act amended TILA to require that ''all compensation paid *directly or indirectly* by a consumer *or creditor* to a mortgage originator from any source, including a mortgage originator that is also the creditor in a table-funded transaction,'' be included in points and fees. TILA section 103(bb)(4)(B) (emphases added). Prior to the amendment, TILA had provided that only compensation paid by a consumer to a mortgage broker at

[114] 78 FR 6856 (Jan. 31, 2013) (2013 HOEPA Final Rule).

[115] The 2013 ATR and HOEPA Final Rules also adopted the special calculation, prescribed under TILA for high-cost mortgages, for completing the bona fide discount point calculation for loans secured by personal property.

[116] The Dodd-Frank Act renumbered existing TILA section 103(aa), which contains the definition of ''points and fees,'' for the high-cost mortgage points and fees threshold, as section 103(bb). *See* section 1100A(1)(A) of the Dodd-Frank Act. However, in defining points and fees for the qualified mortgage points and fees limits, TILA section 129C(b)(2)(C) refers to TILA section 103(aa)(4) rather than TILA section 103(bb)(4). To give meaning to this provision, the Bureau concluded that the reference to TILA section 103(aa)(4) in TILA section 129C(b)(2)(C) is mistaken and therefore interpreted TILA section 129C(b)(2)(C) as referring to the points and fees definition in renumbered TILA section 103(bb)(4).

or before closing should count toward the points and fees threshold for high-cost mortgages. Under amended TILA section 103(bb)(4)(B), however, compensation paid to anyone that qualifies as a ''mortgage originator'' is to be included in points and fees for the points and fees thresholds for both qualified mortgages and high-cost mortgages.[117] Thus, in addition to mortgage brokerage firms, other mortgage originators, including employees of a creditor (*i.e.,* loan officers) or of a brokerage firm (*i.e.,* individual brokers) are included in ''mortgage originator.'' In addition, the Dodd-Frank Act removed the phrase ''payable at or before closing'' from the high-cost mortgage points and fees test and did not apply the ''payable at or before closing'' limitation to the points and fees cap for qualified mortgages. *See* TILA sections 103(bb)(1)(A)(ii) and 129C(b)(2)(A)(vii) and (C).

The 2013 ATR Final Rule. The Bureau's 2013 ATR Final Rule amended § 1026.32(b)(1) to implement revisions to the definition of ''points and fees'' under section 1431 of the Dodd-Frank Act, for the purposes of both HOEPA and qualified mortgages. Among other things, the Dodd-Frank Act added loan originator compensation to the definition of ''points and fees'' that had previously applied to high-cost mortgages under HOEPA. Section 1431 of the Dodd-Frank Act also amended TILA to provide that open-end credit plans (*i.e.,* home equity lines of credit or HELOCs) are covered by HOEPA. The Bureau's 2013 HOEPA Final Rule thus separately amended § 1026.32(b)(2) to provide for the inclusion of loan originator compensation in points and fees for HELOCs, to the same extent as such compensation is required to be counted for closed-end credit transactions. Under § 1026.32(b)(1)(ii) (for closed-end credit) and § 1026.32(b)(2)(ii) (for open-end credit), all compensation paid directly or indirectly by a consumer or creditor to a loan originator, as defined in § 1026.36(a)(1), that can be attributed to that transaction at the time the interest rate is set, is required to be included in points and fees. The commentary to § 1026.32(b)(1)(ii) as adopted in the 2013 ATR Final Rule provides details for applying this requirement for closed-end credit transactions (*e.g.,* by clarifying when compensation must be known to be counted). The commentary to § 1026.32(b)(2)(ii) as adopted in the 2013 HOEPA Final Rule cross-references the commentary adopted in § 1026.32(b)(1)(ii) for interpretive guidance.

In the 2013 ATR Final Rule, the Bureau noted that, in response to the Board's 2011 proposal (Board's 2011 ATR Proposal or Board's proposal)[118] and the Bureau's 2012 proposal to implement the Dodd-Frank Act's amendments to HOEPA,[119] the Bureau received extensive feedback regarding the inclusion of loan originator compensation in the qualified mortgage and high-cost mortgage points and fees calculation. In the context of both rulemakings, several industry commenters argued that including loan originator compensation in points and fees would result in ''double-counting'' because creditors often compensate loan originators with funds collected from consumers at consummation. The commenters argued that money collected in up-front charges to consumers should not be counted a second time toward the points and fees thresholds if it is passed on to a loan originator. Consumer advocates urged the Bureau not to assume that loan originator compensation is funded through up-front consumer payments to creditors rather than through the interest rate. They noted that, in the wholesale channel, if the parties to a transaction would like to fund loan originator compensation through up-front payments, a consumer can pay the mortgage broker directly instead of paying origination charges to the creditor and having the creditor pass through payments to the mortgage broker.

The literal language of TILA section 103(bb)(4) as amended by the Dodd-Frank Act defines points and fees to include all items included in the finance charge (except interest or the time-price differential), all compensation paid directly or indirectly by a consumer or creditor to a loan originator, ''and'' various other enumerated items. The 2013 ATR Final Rule noted that both the use of ''and'' and the reference to ''all'' compensation paid ''directly or indirectly'' and ''from any source'' supports counting compensation as it flows downstream from one party to another so that it is counted each time that it reaches a loan originator, whatever the previous source.

The Bureau stated that it believes the statute would be read to require that loan originator compensation be treated as additive to the other elements of points and fees and should be counted as it flows downstream from one party to another so that it is included in points and fees each time it reaches a loan originator, whatever the previous source. The Bureau indicated that it did not believe that an automatic literal reading of the statute in all cases would be in the best interest of either consumers or industry, but it did not believe that it yet had sufficient information with which to choose definitively between the additive approach provided for in the statutory language and other potential methods of accounting for payments in all circumstances, given the multiple practical and complex policy considerations involved. Accordingly, the Bureau finalized the rule without a qualifying interpretation on this issue and included in the 2013 ATR Proposed Rule several comments to explain how to calculate loan originator compensation in connection with particular payment streams between particular parties. However, the 2013 ATR Final Rule itself implemented the additive approach of the statute.

The 2013 Loan Originator Final Rule. Earlier this year, the Bureau issued a final rule to implement various provisions of the Dodd-Frank Act that addressed compensation paid to loan originators. 78 FR 11280 (Feb. 15, 2013) (2013 Loan Originator Final Rule). As the Bureau noted, the Board had proposed rules in 2009, that, among other things, would have prohibited payments to a loan originator based on the transaction's terms or conditions; prohibited a loan originator from receiving dual compensation (*i.e.,* compensation from both a consumer and another person in the same transaction); and prohibited a loan originator from steering consumers to transactions not in their interest to increase the loan originator's compensation. In section 1403 of the Dodd-Frank Act, Congress amended TILA section 129B to codify significant elements of the Board's 2009 proposal. In a final rule issued in 2010, the Board finalized its proposed rules, while acknowledging that further rulemaking would be required to address certain

[117] ''Mortgage originator'' is generally defined to include ''any person who, for direct or indirect compensation or gain, or in the expectation of direct or indirect compensation or gain—(i) takes a residential mortgage loan application; (ii) assists a consumer in obtaining or applying to obtain a residential mortgage loan; or (iii) offers or negotiates terms of a residential mortgage loan.'' TILA section 103(cc)(2)(A). The statute excludes certain persons from the definition, including a person who performs purely administrative or clerical tasks; an employee of a retailer of manufactured homes who does not take a residential mortgage application or offer or negotiate terms of a residential mortgage loan; and, subject to certain conditions, real estate brokers, sellers who finance three or fewer properties in a 12-month period, and servicers. TILA section 103(cc)(2)(C) through (F).

[118] 76 FR 27390 (May 11, 2011).

[119] 77 FR 49090 (Aug. 15, 2012) (2012 HOEPA Proposal).

issues and adjustments made by the Dodd-Frank Act. 75 FR 58509 (Sept. 24, 2010) (2010 Loan Originator Final Rule). As discussed below, the Bureau's 2013 Loan Originator Final Rule implemented certain provisions of TILA section 129B, including rules expanding and clarifying some of the prohibitions adopted by the Board in the 2010 Loan Originator Final Rule.

The Bureau's 2013 Loan Originator Final Rule clarified the scope of § 1026.36(d)(1), which prohibits basing a loan originator's compensation on any of the transaction's terms. This provision was intended to eliminate incentives for the loan originator to, for example, persuade the consumer to accept a higher interest rate or a prepayment penalty, in exchange for the loan originator receiving higher compensation. The Bureau retained the core prohibition in § 1026.36(d)(1), but it clarified the meaning of a ''term'' of the transaction and clarified the standard for determining when compensation is impermissibly based on a proxy for a term of the transaction. It also permitted certain bonuses and retirement profit-sharing plans to be based on the terms of multiple loan originators' transactions and permitted a loan originator to participate in a defined benefit plan without restrictions on whether the benefits may be based on the terms of a loan originator's transactions. *See* § 1026.36(d)(1)(iii) and (iv). Consistent with the statute, the Bureau also revised § 1026.36(d)(1) so that it also applies in transactions in which the consumer pays a mortgage broker directly.

The 2013 Loan Originator Final Rule also clarified the scope of § 1026.36(d)(2), which prohibits a loan originator from receiving compensation from both the consumer and other persons in the same transaction. This provision was designed to address consumer confusion over mortgage broker loyalties when brokers received payments both from the consumer and the creditor. The 2013 Loan Originator Final Rule retained this prohibition but provided an exception to permit mortgage brokers to pay their employees or contractors commissions (although the commissions cannot be based on the terms of the loans they originate).

In addition, the Bureau used its exception authority to adopt a complete exemption to the statutory ban on up-front fees set forth in TILA section 129B(c)(2)(B)(ii). *See* § 1026.36(d)(2)(ii). That statutory ban would have permitted a loan originator to receive an origination fee or charge from someone other than the consumer only if: (1) The loan originator did not receive any compensation directly from the consumer; and (2) the consumer did not make an up-front payment of discount points, origination points, or fees (other than bona fide third-party charges not retained by the loan originator, creditor, or an affiliate of either). Thus, the Bureau's exemption permits the consumer to pay origination charges or fees to the creditor in transactions in which the creditor is paying compensation to the mortgage broker.

The Bureau also clarified the safe harbor for loan originators to comply with existing § 1026.36(e)(1), which prohibits a loan originator from steering a consumer to consummate a particular transaction so that the loan originator will receive greater compensation. The Bureau clarified how to determine which loans a creditor must offer to consumers to take advantage of the safe harbor. *See* § 1026.36(e)(3)(i)(C) and comment 36(e)(3)–3. The Bureau did not, however, implement the portion of section 1403 of the Dodd-Frank Act that requires the Bureau to prescribe additional regulations to prohibit certain types of steering, abusive or unfair lending practices, mischaracterization of credit histories or appraisals, and discouraging consumers from shopping with other mortgage originators. The Bureau noted that it intends to prescribe those regulations in a future rulemaking. *See* 78 FR 11292 n.55.

The 2013 ATR Proposed Rule

In the 2013 ATR Proposed Rule, the Bureau proposed commentary to address situations in which loan originator compensation passes from one party to another. The Bureau indicated that it believed that Congress included loan originator compensation in points and fees because of concern that loans with high loan originator compensation may be more costly and riskier to consumers. Despite the statutory language, the Bureau questioned whether it would serve the statutory purpose to apply a strict additive rule that would automatically require that loan originator compensation be counted against the points and fees thresholds even if it has already been included in points and fees. The Bureau indicated that it did not believe that it is necessary or appropriate to count the same payment between a consumer and a mortgage broker firm twice, simply because it is both part of the finance charge and loan originator compensation. Similarly, the Bureau indicated that, where a payment from either a consumer or a creditor to a mortgage broker is counted toward points and fees, it would not be necessary or appropriate to count separately funds that the broker then passes on to its individual employees. In each case, any costs and risks to the consumer from high loan originator compensation are adequately captured by counting the funds a single time against the points and fees cap; thus, the Bureau stated that it did not believe the purposes of the statute would be served by counting some or all of the funds a second time, and was concerned that doing so could have negative impacts on the price and availability of credit.

Proposed comment 32(b)(1)(ii)–5.i thus would have provided that a payment from a consumer to a mortgage broker need not be counted toward points and fees twice because it is both part of the finance charge under § 1026.32(b)(1)(i) and loan originator compensation under § 1026.32(b)(1)(ii). Similarly, proposed comment 32(b)(1)(ii)–5.ii would have clarified that § 1026.32(b)(1)(ii) does not require a creditor to include payments by a mortgage broker to its individual loan originator employee in the calculation of points and fees. For example, assume a consumer pays a $3,000 fee to a mortgage broker, and the mortgage broker pays a $1,500 commission to its individual loan originator employee for that transaction. The $3,000 mortgage broker fee is included in points and fees, but the $1,500 commission is not included in points and fees because it has already been included in points and fees as part of the $3,000 mortgage broker fee. The Bureau stated that it believed that any costs to the consumer from loan originator compensation are adequately captured by counting the funds a single time against the points and fees cap. The Bureau sought comment regarding these proposed comments.

The Bureau noted that determining the appropriate accounting method is significantly more complicated when a consumer pays some up-front charges to the creditor and the creditor pays loan originator compensation to either its own employee or to a mortgage broker firm. As described in the 2013 ATR Final Rule, a creditor can fund compensation to its own loan officer or to a mortgage broker in two different ways. First, the payment could be funded by origination charges paid by the consumer to the creditor. Second, the payment could be funded through the interest rate, in which case the creditor forwards funds to the loan originator at consummation which the creditor recovers through profit realized on the subsequent sale of the mortgage or, for portfolio loans, through payments by the consumer over time. Because

money is fungible, tracking how a creditor spends money it collects in up-front charges versus amounts collected through the rate to cover both loan originator compensation and its other overhead expenses would be extraordinarily complex and cumbersome. The Bureau stated that, to facilitate compliance, it believed it would be appropriate and necessary to adopt generalized rules regarding the accounting of various payments, but did not have sufficient information to make those choices in the 2013 ATR Final Rule. However, the 2013 ATR Final Rule itself implemented the additive approach of the statute.

The Bureau noted in the 2013 ATR Proposed Rule that the potential downstream effects of different accounting methods may be significant. Under the ''additive'' approach where no netting of up-front consumer payments against creditor-paid loan originator compensation is allowed, some loans might be precluded from being qualified mortgages or may exceed the high-cost mortgage threshold because of the combination of loan originator compensation with other charges that are included in points and fees, such as fees paid to affiliates for settlement services. In other cases, creditors whose combined loan originator compensation and up-front charges would otherwise exceed the points and fees limits would have strong incentives to cap their up-front charges for other overhead expenses under the threshold and instead recover those expenses by increasing interest rates to generate higher gains on sale. This would adversely affect consumers who prefer to pay a lower interest rate over time in return for higher up-front costs and, at the margins, could result in some consumers being unable to qualify for credit. Additionally, to the extent creditors responded to an ''additive'' rule by increasing interest rates, this could increase the number of qualified mortgages that receive a rebuttable presumption of compliance, rather than a safe harbor from liability, under the ability-to-repay provisions adopted by the 2013 ATR Final Rule.

The Bureau noted that one alternative would be to allow all consumer payments of up-front points and fees to be netted against creditor-paid loan originator compensation. However, this ''netting'' approach would allow creditors to offset much higher levels of up-front points and fees against expenses paid through rate before the heightened consumer protections required by the Dodd-Frank Act would apply. For example, a consumer could pay three percentage points in origination charges and be charged an interest rate sufficient to generate a 3 percent loan originator commission, and the loan could still fall within the 3 percent cap for qualified mortgages. The consumer could be charged five percentage points in origination charges and an interest rate sufficient to generate a 5 percent loan originator commission and still stay under the HOEPA points and fees trigger, thereby denying consumers the special protections afforded to loans with high up-front costs. In markets that are less competitive, this would create an opportunity for creditors or brokerage firms to take advantage of their market power to harm consumers.

The Bureau sought comment on two alternative versions of proposed comment 32(b)(1)(ii)–5.iii. The first—the additive approach—would have explicitly precluded netting, consistent with the literal language of the statute, by specifying that § 1026.32(b)(1)(ii) requires a creditor to include compensation paid by a consumer or creditor to a loan originator in the calculation of points and fees in addition to any fees or charges paid by the consumer to the creditor. This proposed comment contained an example to illustrate this principle: Assume that a consumer pays to the creditor a $3,000 origination fee and that the creditor pays to its loan officer employee $1,500 in compensation attributed to the transaction. Assume further that the consumer pays no other charges to the creditor that are included in points and fees under § 1026.32(b)(1)(i) and the loan officer receives no other compensation that is included in points and fees under § 1026.32(b)(1)(ii). For purposes of calculating points and fees, the $3,000 origination fee would be included in points and fees under § 1026.32(b)(1)(i) and the $1,500 in loan officer compensation would be included in points and fees under § 1026.32(b)(1)(ii), equaling $4,500 in total points and fees, provided that no other points and fees are paid or compensation received.

The second alternative—the netting approach—would have provided that, in calculating the amount of loan originator compensation to include in points and fees, creditors would be permitted to net consumer payments of up-front fees and points against creditor payments to the loan originator. Specifically, it would have provided that § 1026.32(b)(1)(ii) permits a creditor to reduce the amount of loan originator compensation included in the points and fees calculation under § 1026.32(b)(1)(ii) by any amount paid by the consumer to the creditor and included in the points and fees calculation under § 1026.32(b)(1)(i). This proposed comment contained an example to illustrate this principle: Assume that a consumer pays to the creditor a $3,000 origination fee and that the creditor pays to the loan originator $1,500 in compensation attributed to the transaction. Assume further that the consumer pays no other charges to the creditor that are included in points and fees under § 1026.32(b)(1)(i) and the loan originator receives no other compensation that is included in points and fees under § 1026.32(b)(1)(ii). For purposes of calculating points and fees, the $3,000 origination fee would be included in points and fees under § 1026.32(b)(1)(i), but the $1,500 in loan originator compensation need not be included in points and fees. If, however, the consumer pays to the creditor a $1,000 origination fee and the creditor pays to the loan originator $1,500 in compensation, then the $1,000 origination fee would be included in points and fees under § 1026.32(b)(1)(i), and $500 of the loan originator compensation would be included in points and fees under § 1026.32(b)(1)(ii), equaling $1,500 in total points and fees, provided that no other points and fees are paid or compensation received.

The Bureau solicited feedback regarding all aspects of both alternatives. In addition, the Bureau specifically requested feedback regarding whether there are differences in various types of loans, consumers, loan origination channels, or market segments which would justify applying different netting or additive rules to such categories. The Bureau also sought feedback as to whether, if netting were permitted, the creditor should be allowed to reduce the loan originator compensation by the full amount of points and fees included in the finance charge or whether the reduction should be limited to that portion of points and fees denominated as general origination charges.

The Bureau also sought comment on the implications of each alternative on protecting consumers pursuant to the ability-to-repay requirements, qualified mortgage provisions, and the high-cost mortgage provisions of HOEPA. The Bureau also sought comment on the likely market reactions and impacts on the pricing of and access to credit of each alternative, particularly as to how such reactions might affect interest rate levels, the safe harbor and rebuttable presumption afforded to particular qualified mortgages, and application of the separate rate threshold for high-cost mortgages under HOEPA and whether

adjustment to the final rule would be appropriate. The Bureau further sought comment on the implications of both of the above proposed alternatives in light of the fact that both the qualified mortgage and HOEPA provisions allow certain bona fide discount points and bona fide third party charges to be excluded from the calculation of points and fees, but do not do so for affiliate charges.

The Bureau adopted in the 2013 HOEPA Final Rule a requirement that creditors include compensation paid to originators of open-end credit plans in points and fees, to the same extent that such compensation is required to be included for closed-end credit transactions. The Bureau did not receive comments in response to the 2012 HOEPA Proposal indicating that additional or different guidance would be needed to calculate loan originator compensation in the open-end credit context. The Bureau noted in the 2013 ATR Proposed Rule that it would be useful to provide the public with an additional opportunity to comment. Thus, the Bureau solicited input on what guidance, if any, beyond that provided for closed-end credit transactions, would be helpful for creditors in calculating loan originator compensation in the open-end credit context.

Finally, the Bureau sought comment generally on whether additional guidance or regulatory approaches regarding the inclusion of loan originator compensation in points and fees would be useful to protect consumers and facilitate compliance. In particular, the Bureau sought comment on whether it would be helpful to provide for additional adjustment of the rules or additional commentary to clarify any overlaps in definitions between the points and fees provisions in the ability-to-repay and HOEPA rulemakings and the provisions that the Bureau was separately finalizing in connection with the Bureau's 2012 Loan Originator Proposal (since adopted in the 2013 Loan Originator Final Rule). For example, the Bureau sought comment on whether additional guidance would be useful with regard to treatment of compensation by persons who are ''loan originators'' but are not employed by a creditor or mortgage broker, given that the 2013 Loan Originator Final Rule implemented provisions of the Dodd-Frank Act that specify when employees of retailers of manufactured homes, servicers, and other parties are loan originators for Dodd-Frank Act purposes.

Comments Received

The Bureau received numerous comments regarding the calculation of loan originator compensation for inclusion in points and fees for the qualified mortgage and high-cost mortgage points and fees limits. Many of the comments were substantially similar letters submitted by mortgage brokers. Many of the comments responded to the Bureau's proposed commentary regarding potential double counting of loan originator compensation. As described below, however, some comments also raised other issues regarding loan originator compensation.

Few commenters addressed the Bureau's proposed comments 32(b)(1)(ii)–5.i and 32(b)(1)(ii)–5.ii, which would have provided that payments by consumers to mortgage brokers (where those payments already have been included in points and fees under § 1026.32(b)(1)(i)) and payments by mortgage brokers to their individual loan originator employees need not be counted as loan originator compensation and included in points and fees. Nearly all commenters that addressed these proposed comments supported them. One industry commenter, however, argued that the Bureau should not adopt the proposed comments unless the Bureau also excludes from points and fees compensation paid by creditors to their own loan officers. That commenter claimed that it would be inequitable to exclude from points and fees compensation paid to individual loan originators employed by a mortgage broker firm but not to exclude compensation paid to individual loan originators employed by the creditor.

Many more commenters addressed the Bureau's two alternatives for proposed comment 32(b)(1)(ii)–5.iii. Consumer advocates urged the Bureau to adopt an additive approach for transactions in the wholesale channel, *i.e.,* transactions originated through a mortgage broker. They argued that the statutory provision was intended to limit the total up-front charges and loan originator compensation in loans designated as qualified mortgages (and to ensure that loans with charges and compensation above the threshold are subject to the special protection as high-cost mortgages). They maintained that a netting rule would in essence double the points and fees thresholds for qualified mortgages and high-cost mortgages. As a result, loans of $100,000 or more could have up-front charges of 3 percent of the total loan amount and loan originator compensation paid by the creditor equal to another 3 percent, yet the loan could still be a qualified mortgage.[120] Similarly, loans of $20,000 or more could have up-front charges of 5 percent of the total loan amount and creditor-paid compensation equal to another 5 percent, yet the loan would still not qualify as a high-cost mortgage.[121]

Some consumer advocates also argued that consumers have difficulty understanding and evaluating the cost of creditor-paid compensation to mortgage brokers. They contend that, as a result, creditor-paid compensation historically has resulted in more costly loans for consumers, with a higher risk of default, particularly when consumers also have made up-front payments. They argued that an additive rule provides important protection because the Bureau elected in the 2013 Loan Originator Final Rule to permit creditors to continue charging up-front fees to consumers when creditors compensate loan originators. They maintained that a netting rule would encourage creditors and mortgage brokers to combine creditor-paid compensation with up-front charges paid by consumers to creditors because such compensation then would not be included in points and fees. They argued that this combination is less transparent and more confusing to consumers than a model in which the consumer pays a mortgage broker directly or pays all charges through the rate.

Some consumer advocates also argued that the additive approach was necessary to complement the protections contained in § 1026.36(d) and (e) prohibiting or restricting certain loan originator compensation practices. They contended that mortgage brokers could develop problematic business models that would not violate the prohibition in § 1026.36(d)(1) against basing compensation on loan terms and the prohibition in § 1026.36(e) against steering consumers to consummate particular transactions to maximize loan originator compensation. For example, some consumer advocates noted that, without violating these prohibitions, mortgage brokers could specialize in subprime transactions with high up-front charges and high interest rates and could induce creditors to compete for such transactions and offer high loan originator compensation, so long as the compensation did not vary with the

[120] For loans less than $100,000, the qualified mortgage points and fees limits are more than 3 percent of the total loan amount. *See* § 1026.43(e)(3).

[121] For loans less than $20,000, the points and fees thresholds for high-cost mortgages are more than 5 percent of the loan amount. *See* § 1026.32(a)(1)(ii).

terms of individual loans. Alternatively, they suggested that mortgage brokers could do business with a mix of high-cost creditors that pay high compensation and creditors offering more competitive loans that pay lower compensation to brokers. For consumers that mortgage brokers believe would be more likely to agree to more costly loans, mortgage brokers could take advantage of the safe harbor in the anti-steering rules by providing three quotes from high-cost creditors but could continue providing other customers with more competitive loans through other creditors. Consumer advocates argued that an additive approach would deter such practices because creditors charging high up-front fees and paying high compensation to mortgage brokers would find it more difficult to remain below the qualified mortgage points and fees limits and the high-cost mortgage points and fees threshold.

Some consumer advocates also argued that the Bureau lacks the authority to adopt a netting approach for high-cost mortgages under HOEPA. They claimed that the Bureau would need to use its exception authority to adopt the netting approach and that TILA section 105(a) does not permit the Bureau to use its exception authority to modify the items included in points and fees for high-cost mortgages. Thus, they argued that the Bureau can adopt a netting approach only for calculating loan originator compensation for the qualified mortgage points and fees limits. They maintained that creating different measures for loan originator compensation for qualified mortgages and high-cost mortgages would be confusing and create compliance difficulties.

Some consumer advocates also argued that double-counting concerns could be addressed simply by having the consumer pay the mortgage broker directly. They noted that this approach to structuring mortgage pricing would permit a consumer to pay up-front charges to reduce the amount of the interest rate. The consumer payment to the broker would be counted in points and fees only one time. Some consumer advocates maintained that there is little justification for combining creditor-paid compensation to mortgage brokers with up-front charges paid by consumers. They claimed that, historically, the rationale for creditor-paid compensation for mortgage brokers was that it provided an option for consumers that did not have sufficient funds or did not want to pay a mortgage broker directly and instead preferred to pay such compensation through a higher interest rate. They noted that such a rationale does not make sense in a transaction in which creditor-paid compensation is combined with up-front charges paid by the consumer. Some consumer advocates also suggested that double-counting concerns could be addressed by permitting creditors to net origination payments from consumers against loan originator compensation, so long as the creditors provided more detailed disclosures to consumers when such payments would be passed through as compensation to loan originators.

Some consumer advocates argued that the Bureau should treat all loan originators the same and should therefore also adopt an additive rule for transactions in the retail channel. They maintained that, while problematic loan originator compensation practices historically may have been more prevalent in the wholesale channel, there were also similar problems in the retail channel. They also argued that, despite the prohibitions on steering and term-based compensation, creditors will find ways to encourage retail loan officers to steer consumers to higher-cost loans. For example, they suggested that creditors may use deferred compensation plans to provide some incentives for retail loan officers to steer consumers toward higher cost loans. They therefore argued that the same protections provided by an additive approach are necessary in the retail channel.

Some consumer advocates, however, argued that the Bureau should adopt a different rule for transactions in the retail channel. They argued that Congress was particularly concerned with transactions with creditor-paid compensation to mortgage brokers and that such transactions historically tended to be more costly and to have higher rates of default. They claimed that the risks of consumer injury from loan originator compensation practices are significantly lower in the retail channel. They contended that, in the retail channel, creditors and their loan officers would have far greater difficulties in structuring their businesses to evade the prohibitions against steering and term-based compensation in § 1026.36(d)(1) and § 1026.36(e). They noted that retail loan officers cannot pick and choose different loans from different creditors offering different levels of loan originator compensation. They also argued that mortgage brokers may be more successful in convincing consumers to accept more costly loans because consumers perceive that their mortgage broker is a trusted advisor and mistakenly believe that the broker is obligated to provide them with the lowest cost loan.

Some consumer advocates also argued that the double-counting concerns are more pronounced in the retail channel because consumers do not have the option to pay retail loan officers directly. Under an additive approach, any loan originator compensation paid by the creditor to its loan officers would be included in points and fees in addition to any up-front charges paid by the consumer to the creditor. Because the consumer cannot pay up-front charges directly to the retail loan officer, the consumer would have less flexibility to pay up-front charges to receive a lower interest rate and still remain under the points and fees limits.

In developing the final rule, the Bureau consulted with several Federal agencies, as required by section 1022(b)(2)(B) of the Dodd-Frank Act. Three agencies, the Federal Deposit Insurance Corporation (FDIC), HUD, and the Office of the Comptroller of the Currency (OCC) submitted formal comment letters. The FDIC and HUD submitted a joint comment stating their view that compensation paid to mortgage brokers should be included in points and fees whether the consumer pays such compensation directly through up-front charges or indirectly through the creditor and funded through the interest rate. The FDIC and HUD stated that yield spread premiums (YSPs), *i.e.,* compensation paid by a creditor and funded out of the interest rate, have been offered as a payment option for consumers that prefer lower up-front costs and a higher interest rate but that a consumer's choice to use a YSP to compensate a broker should not affect the calculation of loan originator compensation for points and fees. The FDIC and HUD maintained that the netting approach would undercount points and fees. They also stated that a netting approach would create incentives for transactions to include both up-front origination charges and YSPs because the up-front charges could be netted against the YSPs to reduce or eliminate the loan originator compensation that would be included in points and fees. The FDIC and HUD argued that evidence shows that transactions with both up-front charges and ''back-end'' payments tend to be the most costly for consumers and are the most difficult for them to evaluate when shopping for a mortgage.

The FDIC and HUD supported the proposal to exclude compensation paid by a mortgage broker to its employees but argued that the Bureau should also exclude compensation paid by a creditor to its employees. The FDIC and

HUD argued that including in points and fees compensation paid by a creditor to its employee would increase compliance costs and make it difficult for them to create compliant systems by the January 2014 effective date. They also stated that including such compensation in points and fees could result in variations in points and fees for loans with identical costs to the consumer, merely because, for example, one transaction involved a high-performing loan officer. They argued that excluding from points and fees compensation paid by a creditor to its employees would not compromise the consumer protection goals of the points and fees provision because of the loan originator compensation restrictions in § 1026.36(d). They noted that employees of creditors have no ability to choose among creditors, further reducing the risk that consumers would be steered toward more costly loans.

The OCC also submitted a comment stating its support for excluding from points and fees loan originator compensation paid by a consumer to a mortgage broker when that payment already is included in points and fees as part of the finance charge; excluding from points and fees compensation paid by a mortgage broker to its employees; excluding from points and fees compensation paid by a creditor to its employees; and using an additive approach to include in points and fees both origination charges paid by a consumer to a creditor and loan originator compensation paid by a creditor to a mortgage broker. The OCC stated that a netting approach would permit YSPs and origination fees to be charged in the same transaction without including both in points and fees and argued that this would not serve the interest of consumers or of a transparent, competitive mortgage market. The OCC noted that a netting approach would permit a qualified mortgage to have up-front charges equal to 3 percent of the loan amount and an interest rate sufficient to generate a 3 percent loan origination commission; similarly, a netting approach would permit a mortgage loan to have up-front charges equal to 5 percent of the loan amount and an interest rate sufficient to generate a 5 percent loan origination commission. The OCC also maintained that including both origination charges and YSPs increases the complexity of mortgage transactions and confuses consumers, particularly those who are most vulnerable and have the fewest credit choices.

As noted above, the OCC supported excluding from points and fees compensation paid by a creditor to its loan officers. The OCC noted that the banking industry expressed concerns about the operational burden of attempting to track compensation and about the potential uncertainty of whether, because of changes in loan originator compensation, a transaction would be a qualified mortgage. The OCC argued that excluding from points and fees compensation paid by a creditor to its loan officers would not adversely affect consumer protection. The OCC noted that individual employees in both the retail and wholesale channels are prohibited from steering a consumer to a more costly loan to increase their compensation but that there is an added layer of protection because a creditor's loan officers generally do not have the ability to select from different creditors when presenting loan options to consumers.

Repeating arguments they made in response to the Board's 2011 ATR Proposal, many industry commenters, including creditors and their representatives and mortgage brokers and their representatives, again urged the Bureau to exclude loan originator compensation from points and fees altogether. They argued that loan originator compensation has little or no bearing on a consumer's ability to repay a mortgage and that it therefore is unnecessary to include such compensation in points and fees. They also maintained that other regulatory protections, including the prohibition in § 1026.36(d)(1) on compensating loan originators based on the terms of the transaction and the prohibition in § 1026.36(e) on steering consumers to consummate particular transactions to increase loan originator compensation, are sufficient to protect consumers against problematic loan originator compensation practices. They claimed that including loan originator compensation in points and fees would impose a significant compliance burden and make it far more difficult to offer qualified mortgages, leading to higher costs for credit and reduced access to credit.

A trade group representing mortgage brokers and many individual mortgage brokers submitted substantially similar comments recommending that the Bureau exclude all compensation paid by creditors to loan originators. They argued that the Board's 2010 Loan Originator Final Rule already restricted loan originator compensation to prevent steering of consumers to more costly mortgages.

One industry commenter recommended that, if the Bureau declines to exclude all loan originator compensation from points and fees, the Bureau should consider whether compensation paid by a creditor to a mortgage broker should be included in points and fees only for higher-priced mortgage loans because competition may not be as robust for such loans. The commenter suggested that the Bureau consider excluding such compensation entirely from points and fees for mortgage loans in the prime market and excluding only a certain amount for higher-priced mortgage loans.

Many industry commenters advocated that, if the Bureau declines to exclude loan originator compensation altogether, the Bureau should exclude from points and fees any compensation paid to loan originator employees. Many creditors and their representatives argued that compensation paid to loan originators employed by creditors, as well as loan originators employed by mortgage brokers, should be excluded from points and fees. They raised a number of different arguments to support excluding compensation paid to individual loan originators, including retail loan officers.

First, they asserted that calculating loan originator compensation for individual loan originators would impose a substantial burden, particularly for employees of creditors. They noted that retail loan officers often receive a substantial part of their compensation after a mortgage loan is consummated, making it difficult to track and attribute compensation to a transaction before that transaction is consummated. They argued that, for retail loan officers, it would create significant compliance burdens to track compensation paid to each loan officer and attribute that compensation to each transaction. They noted that their existing systems are unable to track and attribute compensation for each loan officer for each transaction, and stated that they would have to develop new systems that could track compensation in real time and communicate with loan origination systems to calculate points and fees. They also asserted that it would impose substantial compliance risk because of the difficulty in accurately calculating such compensation.

Second, they argued that calculating loan originator compensation at the time the interest rate is set would result in an inaccurate measure of compensation and would result in significant anomalies. They noted that various types of compensation, including salary and bonuses based on factors such as loan quality and customer satisfaction, would not be included in loan originator compensation because they cannot be attributed to a particular

transaction. However, they asserted that the amount of compensation that is included in points and fees may have little bearing on how much the consumer actually pays for a given transaction. For example, they noted that two transactions with identical interest rates and up-front charges may nevertheless have different loan originator compensation merely because one transaction involved an experienced, more highly compensated loan officer or because the interest rate in a transaction was set at the end of the month when a loan officer had qualified for a higher commission.

Finally, they argued that employee compensation is merely another overhead cost that already is captured in the interest rate or in origination charges and has little, if any, bearing on a consumer's ability to repay a mortgage. They argued that compensation typically is already captured in points and fees as origination charges and that including employee loan originator compensation would constitute double counting.

One industry commenter recommended that, if the Bureau declines to exclude compensation paid to individual loan originators from points and fees, the Bureau should consider other methods to simplify the calculation of loan originator compensation. That commenter suggested that the Bureau permit a creditor to include as loan originator compensation a fixed amount based on average costs for loan originator compensation over a prior period of time. The commenter noted that such an approach would ease the burden and complexity of tracking compensation for each loan.

A trade group representing mortgage brokers and many individual mortgage brokers submitted substantially similar comments urging the Bureau to include in points and fees only compensation received by the originating entity for loan origination activities. They argued that fees associated with creditors or wholesale lenders should not be included in points and fees. They also maintained that originators should be permitted to charge various percentages for their loan origination activities, provided they do not exceed the qualified mortgage 3 percent cap and that non-bank originators should be permitted to receive compensation from the consumer, creditor, or a combination of both, as long as total compensation does not exceed 3 percent of the loan amount.

Many industry commenters argued that, if the Bureau elects not to exclude loan originator compensation from points and fees altogether, or to exclude compensation paid to loan originator employees, the Bureau should adopt the netting rule in proposed alternative 2 of comment 32(b)(1)(ii)–5.iii. They argued that the additive rule in proposed alternative 1 of comment 32(b)(1)(ii)–5.iii would result in significant double counting and could cause many loans to exceed the qualified mortgage points and fees limits and could cause some loans to exceed the high-cost mortgage threshold.

One commenter asserted that the inclusion of loan originator compensation in points and fees, along with limitations on the number of discount points that may be excluded from points and fees, would limit the ability of nonprofit organizations to assist consumers in obtaining affordable mortgages. The commenter argued that the Bureau should adopt a rule permitting creditors to exclude payments to loan originators if the costs of such payments are absorbed by creditors and not passed along to consumers. As an alternative, the commenter supported comments 32(b)(1)(ii)–5.i and 32(b)(1)(ii)–5.ii, and the second alternative of comment 32(b)(1)(ii)–5.iii, arguing that these comments minimize double-counting. The commenter also urged the Bureau to permit consumers to exclude from points and fees more than two bona fide discount points, recommending that the Bureau exclude from points and fees any amounts used to buy down an interest rate that starts at or below the average 30-year fixed prime offer rate.

Commenters also raised other issues related to loan originator compensation. Several industry and nonprofit commenters requested additional guidance regarding the calculation of loan originator compensation for transactions involving manufactured homes. They noted that, under § 1026.36(a), as amended by the Bureau's 2013 Loan Originator Final Rule, manufactured home retailers and their employees could qualify as loan originators. Industry commenters requested additional guidance on what activities would cause a manufactured home retailer and its employees to qualify as loan originators. They stated that it remains unclear what activities a retailer and its employees could engage in without qualifying as loan originators and causing their compensation to be included in points and fees. Industry commenters also noted that, because the creditor had limited knowledge of and control over the activities of the retailer's employees, it would be difficult for the creditor to know whether the retailer and its employees had engaged in activities that would require their compensation to be included in points and fees. They therefore urged the Bureau to adopt a bright-line rule under which compensation would be included in points and fees only if paid to an employee of a creditor or a mortgage broker.

Industry commenters also requested that the Bureau clarify what compensation must be included in points and fees when a manufactured home retailer and its employees qualify as loan originators. They argued that it is not clear whether the sales price or the sales commission in a transaction should be considered, at least in part, loan originator compensation. They urged the Bureau to clarify that compensation paid to a retailer and its employees in connection with the sale of a manufactured home should not be counted as loan originator compensation.

Finally, a number of industry commenters again advocated excluding certain other items from points and fees. In particular, several industry commenters urged the Bureau to exclude from points and fees real-estate related charges paid to affiliates of the creditor and up-front charges to recover the costs of loan-level price adjustments (LLPAs) imposed by the GSEs.

The Final Rule

The Bureau addresses below various issues regarding the inclusion of loan originator compensation in points and fees. Specifically, the final rule provides that payments by consumers to mortgage brokers need not be counted as loan originator compensation where such payments already have been included in points and fees as part of the finance charge. In addition, compensation paid by a mortgage broker to its employees need not be included in points and fees. The Bureau also concludes that compensation paid by a creditor to its own loan officers need not be included in points and fees. The Bureau determines, however, that it should not use its exception authority to alter the requirement that compensation paid by a creditor to a mortgage broker is included in points and fees in addition to any origination charges paid by a consumer to the creditor. Finally, the Bureau provides further guidance on how to calculate the amount of loan originator compensation for transactions involving manufactured homes.

Compensation paid by consumers to mortgage brokers. In the 2013 ATR Proposed Rule, the Bureau stated that the broad statutory language requiring inclusion of ''all'' compensation paid

''directly or indirectly'' and ''from any source'' supports counting compensation in points and fees each time it is paid to a loan originator. Thus, the Bureau reads the express language of the statute as providing for the inclusion of loan originator compensation in points and fees, even if some or all of that compensation may already have been included in points and fees under other elements of the definition, and the 2013 ATR Final Rule adopted this statutory approach.

However, as noted in the 2013 ATR Proposed Rule, the Bureau does not believe it would be in the interest of consumers or industry to adhere to this ''additive'' approach when it is clear that the compensation already has been captured in points and fees. Thus, as explained below, the Bureau is using its adjustment and exception authority and its authority to revise the criteria that define a qualified mortgage to eliminate double counting in such situations.

As noted above, the Bureau proposed in the 2013 ATR Proposed Rule three different examples (one of which had two alternatives) for calculating loan originator compensation when such compensation may already have been included in points and fees. The first example, proposed comment 32(b)(1)(ii)–5.i, would have provided that a consumer payment to a mortgage broker that is included in points and fees under § 1026.32(b)(1)(i) (because it is included in the finance charge) does not have to be counted in points and fees again under § 1026.32(b)(1)(ii) (as loan originator compensation). The Bureau noted in the 2013 ATR Proposed Rule that it did not believe that counting a single payment to a mortgage broker twice would advance the purpose of the points and fees limits. Few comments addressed this proposed example, and, with one exception, which is discussed below in connection with proposed comment 32(b)(1)(ii)–5.ii, those comments supported the Bureau's proposal that such payments should not be included in points and fees under § 1026.32(b)(1)(ii) if they already are included in points and fees under § 1026.32(b)(1)(i).

The Bureau is therefore adopting comment 32(b)(1)(ii)–5.i as proposed and renumbered as 32(b)(1)(ii)–4.i. The Bureau also is adopting new § 1026.32(b)(1)(ii)(A) to provide that loan originator compensation paid by a consumer to a mortgage broker, as defined in § 1026.36(a)(2), is not included in points and fees if it already has been included in points and fees because it is included in the finance charge under § 1026.32(b)(1)(i). The term ''mortgage broker'' is defined in § 1026.36(a)(2) to mean any loan originator other than an employee of a creditor. Under this definition, persons whose primary business is not originating mortgage loans may nevertheless be mortgage brokers if they qualify as a ''loan originator'' under § 1026.36(a)(1) and are not employees of a creditor. The use of the term ''mortgage broker'' in § 1026.32(b)(1)(ii)(A) is appropriate because compensation is excluded from points and fees under § 1026.32(b)(1)(ii)(A) only if such compensation already has been included in points and fees under § 1026.32(b)(1)(i).

The Bureau is adopting new § 1026.32(b)(1)(ii)(A) pursuant to its authority under TILA section 105(a) to make such adjustments and exceptions for any class of transactions as the Bureau finds necessary or proper to facilitate compliance with TILA and to effectuate the purposes of TILA, including the purposes of TILA section 129C of ensuring that consumers are offered and receive residential mortgage loans that reasonably reflect their ability to repay the loans. The Bureau's understanding of this purpose is informed by the findings related to the purposes of section 129C of ensuring that responsible, affordable mortgage credit remains available to consumers. The Bureau believes that using its exception authorities to ensure that a single payment to a mortgage broker will not be counted twice in points and fees will facilitate compliance with the points and fees regulatory regime by allowing creditors to count the payment to a broker once without requiring further investigation into the mortgage broker's employee compensation practices, and by making sure that all creditors apply the provision consistently. It will also effectuate the purposes of TILA by preventing the points and fees calculation from being artificially inflated, thereby helping to keep mortgage loans available and affordable by ensuring that they are subject to the appropriate regulatory framework with respect to qualified mortgages and the high-cost mortgage threshold. The Bureau is also invoking its authority under TILA section 129C(b)(3)(B) to revise, add to, or subtract from the criteria that define a qualified mortgage consistent with applicable standards. For the reasons explained above, the Bureau has determined that it is necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C and necessary and appropriate to effectuate the purposes of this section and to facilitate compliance with section 129C. With respect to its use of TILA section 129C(b)(3)(B) here and elsewhere in this section, the Bureau believes this authority includes adjustments and exceptions to the definitions of the criteria for qualified mortgages and that it is consistent with the purpose of facilitating compliance to extend use of this authority to the points and fees definitions for high-cost mortgage in order to preserve the consistency of the qualified mortgage and high-cost mortgage definitions. As noted above, by helping to ensure that the points and fees calculation is not artificially inflated by counting a single payment to a mortgage broker twice, the Bureau is helping to ensure that responsible, affordable mortgage credit remains available to consumers.

Some consumer advocates argued that the Bureau lacks exception authority to exclude loan originator compensation from the points and fees calculation for the high-cost mortgage threshold under HOEPA.[122] However, while the Bureau's authority under TILA section 105(a) does not extend to the substantive protections for high-cost mortgages in TILA section 129, the provision that defines high-cost mortgages, including the points and fees definitions, is part of TILA section 103. Thus, although the Bureau cannot use its authority under TILA section 105(a) to alter the substantive protections accorded to high-cost mortgages under TILA section 129, it can use that authority to adjust the criteria used to define a high-cost mortgage, including the method for calculating points and fees, as specified elsewhere in TILA.

Compensation paid by mortgage brokers to their loan originator employees. The second example, proposed comment 32(b)(1)(ii)–5.ii, would have provided that compensation paid by a mortgage broker to its individual loan originator employees is not included in points and fees under § 1026.32(b)(1)(ii). The Bureau stated in the 2013 ATR Proposed Rule that the exclusion from points and fees was warranted because a payment from

[122] The consumer advocate commenters made this argument to oppose the Bureau's using exception authority to exclude from points and fees (or use a netting approach for) compensation paid by creditors to loan originators. However, because this argument would also apply to the Bureau's use of exception authority to exclude from points and fees compensation paid by a consumer to a mortgage broker or by a mortgage broker to its employees, the Bureau addresses this argument here with respect to this and other uses of its exception authority in this rulemaking to exclude certain loan originator compensation from points and fees.

either a consumer or creditor to a mortgage broker firm already is counted in points and fees, and that it would not be necessary or appropriate to also include in points and fees any funds that the mortgage broker firm passes on to its individual loan originator employees. Again, few commenters addressed this example, and, with one exception, they supported the Bureau's proposed comment.

As noted above, one creditor argued that it would be unfair to adopt proposed comments 32(b)(1)(ii)–5.i and 32(b)(1)(ii)–5.ii without adopting a similar exclusion for compensation paid by a creditor to its employee loan originators (*i.e.,* its own loan officers). For the reasons set forth below, the Bureau is using its exception authority to permit creditors to exclude from points and fees compensation paid to their own loan officers.

Accordingly, the Bureau is adopting comment 32(b)(1)(ii)–5.ii substantially as proposed and renumbered as 32(b)(1)(ii)–4.ii, and is adopting new § 1026.32(b)(1)(ii)(B) to provide that a payment from a mortgage broker, as defined in § 1026.36(a)(2), to a loan originator who is an employee of the mortgage broker is not included in points and fees. As noted above, the term ''mortgage broker'' is defined in § 1026.36(a)(2) to mean any loan originator other than an employee of a creditor. Under this definition, persons whose primary business is not originating mortgage loans may nevertheless be mortgage brokers if they qualify as a ''loan originator'' under § 1026.36(a)(1) and are not employees of a creditor. To qualify as a loan originator under § 1026.36(a)(1), a person must engage in loan origination activities in expectation of compensation. The use of the term ''mortgage broker'' in § 1026.32(b)(1)(ii)(B) is appropriate because, as discussed above, compensation that a mortgage broker receives from a consumer or creditor is included in points and fees, and this compensation provides the funds for any compensation that is paid by the mortgage broker to its employee.

TILA section 103(bb)(4)(B) provides that compensation paid by a ''consumer or creditor'' to a loan originator is included in points and fees. The Bureau notes that a mortgage broker firm is neither a consumer nor a creditor, so the statute could plausibly be read so that points and fees would not include payments from a mortgage broker firm to loan originators who work for the firm. However, TILA section 103(bb)(4)(B) provides that compensation must be included in points and fees if it is paid ''directly or indirectly'' by a consumer or creditor ''from any source.'' Because compensation by a mortgage broker firm to its employees is funded from consumer or creditor payments, such compensation could be interpreted as being paid indirectly by a consumer or creditor.

Given the ambiguity, the Bureau is also invoking its authority under TILA section 105(a) to make such adjustments and exceptions for a class of transactions as the Bureau finds necessary or proper to facilitate compliance with TILA and to effectuate the purposes of TILA, including the purposes of TILA section 129C of ensuring that consumers are offered and receive residential mortgage loans that reasonably reflect their ability to repay the loans. The Bureau's understanding of this purpose is informed by the findings related to the purposes of section 129C of ensuring that responsible, affordable mortgage credit remains available to consumers. Because payments by mortgage brokers to their employees already have been captured in the points and fees calculation, excluding such payments will facilitate compliance with the points and fees regulatory regime by eliminating the need for further investigation into the mortgage brokers' employee compensation practices, and by making sure that all creditors apply the provision consistently. It will also effectuate the purposes of TILA by preventing the points and fees calculation from being artificially inflated, thereby helping to keep mortgage loans available and affordable by ensuring that they are subject to the appropriate regulatory framework with respect to qualified mortgages and the high-cost mortgage threshold. The Bureau is also invoking its authority under TILA section 129C(b)(3)(B) to revise, add to, or subtract from the criteria that define a qualified mortgage consistent with applicable standards. For the reasons explained above, the Bureau has determined that it is necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C and necessary and appropriate to effectuate the purposes of this section and to facilitate compliance with section 129C.

Compensation paid by creditors. As noted in the 2013 ATR Proposed Rule, it is significantly more complicated to devise a rule for calculating loan originator compensation when the consumer pays some up-front charges to the creditor and the creditor pays loan originator compensation to either its own loan officer or to a mortgage broker. That is because the creditor can fund the compensation in two different ways: either through origination charges paid by the consumer (which would be included in points and fees) or through the interest rate (which would not be included in points and fees). There is no practicable method for the Bureau to determine by rule the extent to which compensation paid by the creditor was funded through origination charges and, thereby, already captured in the points and fees calculation. The Bureau therefore indicated that it believed that bright-line rules would be necessary to facilitate compliance.

As discussed below, the Bureau concludes that it is appropriate to apply different requirements to loan originator compensation paid by the creditor to its own loan officers and to compensation paid by the creditor to other loan originators. Specifically, the Bureau is using its exception authority to exclude from points and fees compensation paid by the creditor to its own loan officers. Compensation paid by the creditor to other loan originators is included in points and fees, and such compensation must be counted in addition to any up-front charges that are included in points and fees.

Compensation paid by creditors to their own loan officers. In response to the Board's 2011 ATR Proposal, many creditors and organizations representing creditors urged the Bureau to exclude all compensation paid to individual loan originators. Among other things, these commenters had argued that compensation paid to loan originators already is included in the cost of loan, either in the interest rate or in origination charges; that having to track individual loan originators' compensation and attribute it to specific transactions would impose a significant compliance burden; and that including compensation paid to individual loan originators would cause anomalous results, with otherwise identical loans having different amounts of loan originator compensation included in points and fees because of the timing of the loan or the identity of the loan originator. *See* 78 FR 6433–34 (Jan. 30, 2013).

In the 2013 ATR Final Rule, the Bureau acknowledged the concerns about including in points and fees compensation paid to individual loan originators. Nevertheless, the Bureau declined to exclude such compensation, noting that the statutory language provided that points and fees include compensation paid to ''mortgage originators,'' which is defined to

include individual loan officers. *Id.* at 6436. The Bureau also noted that excluding from points and fees compensation paid by creditors to their loan officers would exacerbate the differential treatment between the retail and wholesale channels, as creditors in retail transactions would not be required to include any loan originator compensation in points and fees, while creditors in wholesale transactions would be required to include in points and fees compensation paid by either consumers or creditors to mortgage brokers. *Id.*

The Bureau notes that, in responding to the Board's 2011 ATR Proposal, commenters did not have the benefit of considering how including loan originator compensation in points and fees would interact with the rules regarding loan originator compensation that were proposed by the Bureau in the 2012 Loan Originator Proposal and finalized in the 2013 Loan Originator Final Rule. In response to the 2013 ATR Proposed Rule, the Bureau received detailed comments analyzing whether, in light of the protections in the 2013 Loan Originator Final Rule, it would be appropriate to include various types of loan originator compensation in points and fees. The Bureau also received more extensive explanations from creditors and organizations representing creditors about the difficulties of calculating compensation paid by creditors to their own loan officers.

After carefully considering the comments received in response to the 2013 ATR Proposed Rule, the Bureau believes it is appropriate to reconsider whether compensation paid to individual loan originators should be excluded from points and fees. As noted above, the Bureau already has determined that compensation paid by a mortgage broker to its loan originator employees need not be included in points and fees. The Bureau concludes that it should use its exception authority to exclude the compensation that creditors pay to their loan officers from points and fees as well. As discussed in more detail below, the Bureau determines that including compensation paid by creditors to their loan officers in points and fees at this time not only would impose a severe compliance burden on the industry, but also would lead to distortions in the market for mortgage loans and produce anomalous results for consumers. The Bureau also believes that there are structural and operational reasons why not including in points and fees compensation paid to retail loan officers poses a limited risk of harm to consumers. As a result, the Bureau believes that including such compensation in points and fees would not effectuate the purposes of the statute and in fact would frustrate efforts to implement and comply with the points and fees limits and with the broader statutory and regulatory regime for qualified mortgages and high-cost mortgages that must be implemented by January 2014. The Bureau has decided at this time to exclude compensation paid by creditors to their own loan officers. The Bureau will continue to gather data to determine the need for and the best method for counting compensation paid by creditors to their loan officers consistent with the purpose of the statute. The Bureau will closely monitor the market as it considers this issue to determine if further action is warranted.

As indicated above, several factors support this conclusion.[123] Attributing overall individual loan officer compensation to specific transactions is an extraordinarily difficult task. The Bureau considered these difficulties in the 2013 ATR Final Rule, when it revised § 1026.32(b)(1)(ii) to provide that creditors must include in points and fees loan originator compensation that can be attributed to that transaction at the time the interest rate is set. The requirement that the compensation is included only if it can be attributed to the transaction at the time the interest rate is set was intended to permit creditors to calculate compensation sufficiently early in the process so that they could know well before consummation whether a loan would be a qualified mortgage or a high-cost mortgage. *See* 78 FR 6437 (Jan. 30, 2013). This calculation is straightforward for compensation paid by creditors to mortgage brokers: For each transaction, creditors typically pay a commission to mortgage brokers pursuant to a pre-existing contract between the creditor and the broker, and that commission is known at the time the interest rate is set. Furthermore, because the commission structure is known in advance it can be built into the price of the loan, either through up-front charges or through the interest rate.

The calculation of loan originator compensation is significantly more complicated for retail loan officers.[124] As noted by industry commenters, compensation for retail loan officers often is not determined until after the end of the month or some other, longer time period (such as a quarter) and in many cases is based upon the number or dollar volume of the transactions that have been consummated during the preceding month or other time period. However, for purposes of determining whether a particular transaction is a qualified mortgage (or a high-cost mortgage), the calculation of points and fees (and thus loan originator compensation) must be performed prior to consummation. Thus, to calculate loan originator compensation for retail loan officers for purposes of applying the qualified mortgage and high-cost mortgage thresholds, creditors would have to determine, at the time the interest rate is set, what compensation a retail loan officer would be entitled to receive if a particular transaction were consummated. As noted above, this calculation often would be based on the number or dollar amount of transactions already consummated during the time period in which compensation is set (*e.g.,* the month or quarter or other time period). This calculation may produce an artificial measure of compensation because, for the transaction for which compensation is being calculated, the date the interest rate is set may fall in a different time period than the date the transaction is consummated and actual compensation is set.[125] If the interest rate were to be reset (if, for example, a rate lock expires or underwriting identifies risk factors which leads to an increase in the interest rate), the compensation would have to be recalculated.

[123] Some creditors and organizations representing creditors had argued that it would be appropriate to exclude from points and fees compensation paid by creditors to their loan officers because compensation paid to loan originator employees of a mortgage brokerage firm would also be excluded. As noted above, compensation paid to employees of mortgage brokerage firms is excluded from points and fees because such compensation already is captured in points and fees in the payments by consumers or creditors to the mortgage brokerage firms. By contrast, as noted above, compensation paid to a retail loan officer may be funded either through origination charges or through the interest rate, so there is no guarantee that such compensation already has been included in points and fees. As discussed below, however, the Bureau concludes that additional factors justify excluding from points and fees compensation paid by creditors to their own loan officers.

[124] The calculation of compensation paid by mortgage brokerage firms to their individual loan originator employees could be similarly complicated. However, as discussed above, the Bureau is excluding such compensation from points and fees because such compensation already has been captured in the points and fees calculation.

[125] The Bureau recognizes that a more accurate measure of compensation could be calculated at the time of consummation. However, as noted in the 2013 ATR Final Rule, creditors need to know in advance of consummation whether a transaction will be a qualified mortgage or a high-cost mortgage and therefore need to be able to calculate loan originator compensation, and points and fees generally, prior to consummation. Thus, the Bureau does not believe that is appropriate to require that loan originator compensation be calculated at consummation.

The Bureau understands from industry comments that creditors' existing systems generally do not track compensation for each loan officer for each specific transaction. Thus, creditors would have to develop new systems or reprogram existing systems to track and attribute compensation for each transaction. Depending on the compensation structure, these systems would have to be dynamic so that they could track at the time the interest rate is set what compensation a loan officer would be entitled to receive if a given transaction were consummated.[126] Further, the systems would have to feed into the creditors' origination systems so that the points-and-fee calculation could be made. The Bureau is also concerned that creditors may have difficulty in implementing these systems by January 2014, when the ATR Final Rule becomes effective.

In addition, the Bureau is concerned that requiring creditors to calculate loan originator compensation for their loan officers may create uncertainty about the points and fees calculations and thus about whether loans satisfy the standards for qualified mortgages and remain below the threshold for high-cost mortgages. As noted above, if compensation paid to creditors' loan officers were included in points and fees, creditors would have to calculate at the time the interest rate is set what compensation a loan officer would be entitled to receive in the future. This compensation often would depend on the timing of other loans (*i.e.,* how many loans have been consummated or the dollar value of loans consummated by the loan officer at the time the interest rate is set), introducing complexity and potential for errors into the calculation. Moreover, counting retail compensation in points and fees would introduce significant uncertainty into transactions in which the interest rate is not locked well in advance of consummation. For instance, if the consumer elected at the time of application to allow the interest rate to float, the interest rate may not be set until several days before consummation. In such cases, the creditor might be uncertain as to whether the transaction was a qualified mortgage or a high-cost mortgage until that time. Similarly, even if the interest rate is locked in early in the process, it may subsequently be re-set, either because the rate lock expires or because the terms of the transaction are renegotiated after underwriting. In those cases, a transaction that was expected to be a qualified mortgage may lose that status because the loan originator compensation is recalculated at the time the interest rate is finally set. The uncertainty of calculating compensation highlights the difficulty creditors would face in complying with a rule that includes compensation to the creditors' employees in points and fees, and the Bureau is concerned that this uncertainty could be disruptive to the market.

The burden and uncertainty of requiring creditors to calculate loan originator compensation for their loan officers with respect to each individual transaction as of the time the interest rate is set are of particular concern because it does not appear that this calculation would further the purposes of the statute. The Bureau believes that Congress expanded the scope of loan originator compensation to be included in points and fees because of concerns that a loan with high loan originator compensation is likely to be more costly and may pose greater risk for consumers. However, for the reasons discussed below, the Bureau does not believe that calculating at the time the interest rate is set the compensation to be paid by creditors to their own loan officers is likely to be an accurate measure of the actual compensation the loan officer will receive if the loan is consummated or of the costs passed along to consumers.

First, the compensation as calculated may be inaccurate and incomplete. As noted above, compensation would be calculated at the time the interest rate is set, so the actual compensation that a loan officer would receive may be different from the amount that would be included in points and fees. Moreover, various types of compensation, such as salary and bonuses for factors such as loan performance and customer satisfaction, cannot be attributed to specific transactions and therefore would not be included in loan originator compensation for calculating points and fees. As a result, the calculation would produce an incomplete measure of compensation, and creditors would have substantial flexibility to restructure their compensation systems to reduce the amount of loan originator compensation that they would have to include in points and fees. To the extent that increasing numbers of creditors were to restructure compensation to avoid the impact of the rules, the inclusion of loan originator compensation in points and fees would become even less meaningful or consistent over time.

Second, because of the limitations on calculating compensation, counting retail loan originator compensation in points and fees would produce arbitrary outcomes because the amount of compensation that would be attributed to a particular transaction often will be unrelated to the costs or risks borne by the consumer. For example, two retail transactions with identical interest rates and up-front charges could have different loan originator compensation, and therefore different points and fees, simply because a senior, more highly compensated loan officer was involved in one of the transactions. Similarly, two transactions involving the same loan officer could have different loan originator compensation amounts depending on whether the interest rates are set at the end of the month, when the loan officer might qualify for a higher commission for meeting a monthly quota for loans closed, rather than at the beginning of the month, when such a quota is unlikely to have been met.[127] By contrast, the costs to the consumer, as reflected in origination charges and the interest rate, are not likely to vary based on the seniority of the loan originator handling the transaction or the loan officer's satisfaction of the creditor's monthly quota for obtaining a higher commission.

The Bureau is also concerned that including in points and fees compensation paid by a creditor to its own loan officer would place additional limits on consumers' ability to structure their preferred combination of up-front charges and interest rate. The points and fees limits themselves restrict consumers' ability to pay up-front charges and still obtain a qualified mortgage (or avoid a high-cost mortgage). However, these limits would permit even less flexibility in the retail channel because consumers cannot pay retail loan officers directly. For example, assume a consumer is seeking a $100,000 loan and wants to pay $2,500 in up-front charges at closing rather than paying those costs through a higher

[126] Moreover, the Bureau understands that some consumers prefer to float the interest rate and other consumers lock their interest rate but have the right to relock one time at a lower rate. Thus, in these circumstances, creditors would have to calculate (or recalculate) loan originator compensation later in the process.

[127] Another arbitrary result could occur when a consumer relocks at a lower interest rate. At the time of the initial rate set, the creditor could calculate loan originator compensation and determine that points and fees do not exceed the qualified mortgage points and fees limit or the high-cost mortgage threshold. However, after the rate is reset, the creditor would have to recalculate loan originator compensation, and, if the loan originator has satisfied a creditor's monthly quota for obtaining a higher commission, it is possible that the higher loan originator compensation could cause the points and fees to exceed the qualified mortgage limits (or the high-cost mortgage threshold).

interest rate. Assume that the up-front charges would all be included in points and fees and that the transaction is being originated through a creditor's loan officer, whose compensation is $1,500. Under an additive approach, if the consumer pays $2,500 in origination charges to the creditor and the creditor pays $1,500 to its loan officer, the points and fees would be $4,000 and the loan could not be a qualified mortgage. In contrast with a transaction originated through a mortgage broker, the consumer would not have the option of paying $1,500 directly to the loan officer. The $1,500 in loan originator compensation would count toward the points and fees limits, so the consumer therefore would not be able to pay all of the $2,500 up-front without exceeding the points and fees limit for a qualified mortgage.[128] The consumer would have to pay other costs through a higher interest rate and the resulting higher monthly payments. Thus, under an additive rule, consumers in the retail channel would have less flexibility to pay up-front charges to achieve a lower interest rate and have the transaction remain below the points and fees limits for qualified mortgages and below the threshold for high-cost mortgages. For certain consumers, such as those who do not qualify for a higher interest rate, the impact could affect their access to credit. Excluding from points and fees loan originator compensation paid by a creditor to its loan officers would address this concern.

The Bureau recognizes that creditors may earn greater profits when consumers receive more costly loans and that, in the absence of regulatory protections, creditors could adopt compensation arrangements that create incentives for their loan officers to originate loans that are more costly for consumers. Including loan officer compensation in points and fees would have imposed some limits on the ability of creditors to offer higher compensation to its loan officers. The Bureau believes, however, that the prohibition on terms-based compensation in § 1026.36(d)(1) will provide substantial protection against problematic loan originator compensation practices in the retail channel. The Bureau concludes that these protections will significantly diminish the risk of consumer injury from excluding from points and fees compensation paid by creditors to their retail loan officers. The prohibition in § 1026.36(d)(1) prevents a creditor from paying higher compensation to its loan officer for a transaction that, for example, has a higher interest rate or higher up-front charges. Moreover, the Bureau agrees with consumer advocate commenters and comments by the FDIC and HUD and by the OCC that argue that retail loan officers would have greater difficulty than mortgage brokers in trying to maneuver around the margins of § 1026.36(d)(1). Unlike a mortgage broker, a retail loan officer works with only one creditor and therefore cannot choose among different creditors paying different compensation in deciding which loans to offer a consumer.

As noted above, some consumer advocates argued that creditors would still be able to structure loan originator compensation to create incentives for their loan officers to direct consumers toward higher-cost loans. For example, they noted that the 2013 Loan Originator Final Rule adopted § 1026.36(d)(1)(iii) and (iv), which permit creditors to offer, under certain conditions, deferred compensation plans and non-deferred profits-based compensation to their loan officers that otherwise would violate the prohibition on term-based compensation. They suggested that such arrangements could be structured to encourage loan officers to induce consumers to accept more costly loans. The Bureau is sensitive to the risk that unscrupulous creditors may look for gaps and loopholes in regulations; however, the Bureau notes that the referenced provisions of § 1026.36(d)(1) were carefully crafted to attenuate any incentives for directing consumers to higher-cost loans to increase compensation. The Bureau recognizes that creditors have significant incentives to work around the margins of the rules and, as noted above, is committed to monitoring compensation practices closely for problematic developments that may require further action.

In light of these concerns about the significant compliance burden and the questionable accuracy of the calculation for retail loan officer compensation, the Bureau believes it is appropriate at this time to exclude such compensation from points and fees. The Bureau will continue to monitor and gather information about loan originator compensation practices to determine if there are methods that are practicable and consistent with the purposes of the statute for including in points and fees loan originator compensation paid by creditors to their loan officers. As part of the Bureau's ongoing monitoring of the mortgage market and for the purposes of the Dodd-Frank Act section 1022(d) five-year review, the Bureau will assess how the exclusion from points and fees of compensation paid by creditors to their loan officers is affecting consumers. If the Bureau were to find that the exclusion for retail loan officer compensation was harming consumers, the Bureau could issue a new proposal to narrow or eliminate the exclusion. The Bureau is aware that problematic loan originator compensation practices occurred in the past in the retail channel and that questionable practices may occur again. The Bureau will carefully monitor the marketplace to respond to any such abusive practices, including through the use of its supervisory and enforcement authority.

The Bureau stated in the 2013 ATR Final Rule that it was reluctant to exclude from points and fees compensation paid to individual loan originators because it would treat the retail and wholesale channels differently. As discussed above, however, after considering the information received in response to the 2013 ATR Proposed Rule, the Bureau believes there are significant difficulties in calculating loan originator compensation in the retail channel. By contrast, in transactions involving mortgage brokers, there is little compliance burden in calculating loan originator compensation, and compensation typically can be calculated with relative ease and accuracy. Moreover, the Bureau believes that there is less risk of consumer injury from excluding loan originator compensation from points and fees in the retail channel. The Bureau is concerned that that mortgage brokers may have the flexibility to structure their business model to evade the prohibitions of § 1026.36(d)(1) and § 1026.36(e) and that the risk of consumer injury from problematic loan originator compensation practices is therefore higher in the wholesale channel than in the retail channel. The Bureau is also concerned that unscrupulous creditors seeking to originate more costly loans could use the wholesale channel to expand their operations more rapidly and with limited investment. Historical evidence also suggests that the risks of consumer injury may be greater in the wholesale channel. As noted above, some consumer advocates cited evidence that, particularly in the subprime market, loans originated with mortgage brokers were on average more expensive and more likely to default than loans

[128] If the consumer's payments satisfy the standards of § 1026.32(b)(1)(i)(E) or (F), the up-front fees could be excluded from points and fees as bona fide discount points.

originated in the retail channel.[129] Thus, for the reasons discussed above, the Bureau believes that it is necessary and proper to use its exception authority to exclude from points and fees compensation paid by creditors to their loan officers.

The Bureau considered options other than excluding from points and fees compensation paid by a creditor to its loan officers. The Bureau considered adopting a netting rule for compensation paid by a creditor to its loan officers. This approach would have addressed the concern that an additive methodology would unduly restrict a consumers' ability to structure their preferred combination of up-front charges and interest rate. However, a netting rule would not alleviate the compliance burden or address the other implementation concerns associated with including in points and fees compensation paid by creditors to their loan officers. One industry commenter recommended that, if the Bureau declines to exclude compensation paid to retail loan officers from points and fees, it should consider permitting creditors to include in points and fees an average measure of loan originator compensation over a prior period of time as an alternative to calculating compensation on a transaction-by-transaction basis. The Bureau considered such an approach as an alternative for alleviating the compliance burden and eliminating some of the anomalies between transactions. However, the Bureau has concerns about whether this approach is consistent with the statutory purpose of identifying transactions that, because of high up-front charges and high loan originator compensation, should not be eligible for the presumption of compliance of a qualified mortgage or that should receive the protections for high-cost mortgages. Moreover, permitting creditors to employ an average measure of loan originator compensation would raise significant issues. For example, the Bureau would have to determine what compensation would be included in the measure of average compensation, the period for which the average would be calculated, and whether the average would be for an entire firm, for a business unit, for a limited geographic area, or even for individual loan originators. In light of the limited time remaining before the effective date of the rules, the Bureau does not believe it would be practicable to attempt to implement this alternative.

To implement the exclusion from points and fees of compensation paid by a creditor to its loan officers, the Bureau is adding new § 1026.32(b)(1)(ii)(C), which excludes compensation paid by a creditor to a loan originator that is an employee of the creditor. The Bureau also is adding language to comment 32(b)(1)(ii)-1 to clarify that compensation paid by a creditor to a loan originator that is an employee of the creditor is not included in points and fees.

As the Bureau noted in the 2013 ATR Final Rule, the Dodd-Frank Act provides that points and fees include all compensation paid by a consumer or creditor to a ''mortgage originator.'' In addition, as noted above, the Bureau reads the statutory language as requiring that loan originator compensation be included in points and fees in addition to any other items that are included in points and fees, even if the loan originator compensation may have been funded through charges that already are included in points and fees. Moreover the Bureau reads the statutory provision on compensation as meaning that compensation is added as it flows downstream from one party to another so that it is counted each time that it reached a loan originator, whatever its previous source. Given this statutory language, the Bureau believes that, to exclude from points and fees compensation paid by a creditor to its loan officers, the Bureau must use its exception authority. As provided in new § 1026.32(b)(1)(ii)(C), the Bureau is excluding compensation paid by creditors to their loan officers pursuant to its authority under TILA section 105(a) to make such adjustments and exceptions for a class of transactions as the Bureau finds necessary or proper to facilitate compliance with TILA and its purposes and to effectuate the purposes of TILA, including the purposes of TILA section 129C of ensuring that consumers are offered and receive residential mortgage loans that reasonably reflect their ability to repay the loans. The Bureau's understanding of this purpose is informed by the findings related to the purposes of section 129C of ensuring that responsible, affordable mortgage credit remains available to consumers. The Bureau has determined that excluding compensation paid to retail loan officers will facilitate compliance with TILA and these purposes by helping to reduce the burden and uncertainty of calculating points and fees in the retail context and by helping to assure that, as of the effective date of the rule, creditors will have systems in place that are capable of making this calculation. At the same time, the Bureau has determined that excluding compensation paid to retail loan officers will effectuate the purposes of TILA by helping to ensure that loans are not arbitrarily precluded from satisfying the criteria for a qualified mortgage or arbitrarily designated as high-cost mortgages because of potential anomalies in how loan originator compensation would be calculated for the points and fees limits. Thus, the exclusion will help ensure the availability of reasonably repayable credit, given that the points and fees threshold will continue to provide limits, apart from compensation not included in finance charge, on costs related to loans.

The Bureau is also relying upon its authority under TILA section 129C(b)(3)(B) to revise, add to, or subtract from the criteria that define a qualified mortgage consistent with applicable standards. For the reasons explained above, the Bureau has determined that it is necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C and necessary and appropriate to effectuate the purposes of this section and to facilitate compliance with section 129C.

Certain commentary adopted in the 2013 ATR Final Rule is no longer necessary in light of the Bureau's decisions discussed above. Comment 32(b)(1)(ii)–2 describes certain types of

[129] *See, e.g.,* Keith Ernst, Debbie Bocian, Wei Li, Ctr. for Responsible Lending, *Steered Wrong: Brokers, Borrowers, and Subprime Loans* (2008); Antje Berndt, Burton Hollifield, and Patrik Sandas, *What Broker Charges Reveal About Mortgage Credit Risk,* (2012); Susan E. Woodward, A Study of Closing Costs for FHA Mortgages available at *http://www.huduser.org/Publications/pdf/FHA_closing_cost.pdf.* The Bureau's review of studies generally supports this view, though the evidence is not unequivocal. Wei Jiang, Ashlyn Aiko Nelson, and Edward Vytacil, *Liar's Loan? Effects of Origination Channel and Information Falsification on Mortgage Delinquency,* SSRN working paper 142162 (2009) use a dataset from one bank with approximately 700,000 loans originated between 2004 and 2008. They report that ''the Broker subsamples have delinquency probabilities that are 10–14 percentage points (or more than 50%) higher than the Bank subsamples, a manifestation of the misalignment of incentives for brokers who issue loans on the bank's behalf for commissions but do not bear the long-term consequences of low-quality loans.'' They also show that loan pricing does not compensate for the loan performance differences. Michael LaCour-Little, *The Pricing of Mortgages by Brokers: An Agency Problem?,* J. of Real Estate Research, 31(2), 235–263 (2009) showcases the agency problems in the brokerage channel, and provides a deep literature review. This paper's results ''suggest loans originated by brokers cost borrowers about 20 basis points more, on average, than retail loans and that this premium is higher for lower-income and lower credit score borrowers.'' In contrast, Amany El-Anshany, Gregory Elliehausen, and Yoshiaki Shimazaki, *Mortgage Brokers and the Subprime Mortgage Market,* Proceedings, Federal Reserve Bank of Chicago (2005), find that consumers buying through brokers paid less for their loans, by a similar magnitude as in the LaCour-Little paper.

compensation that would and would not be included in points and fees for individual loan originators. Portions of comment 32(b)(1)(ii)–3 discuss how the timing affects what compensation paid to individual loan originators must be included in points and fees. Comment 32(b)(1)(ii)–4 provides examples for calculating compensation for individual loan originators. Because compensation paid by mortgage brokers to their individual loan originator employees and compensation paid by creditors to their loan officers is no longer included in points and fees, the guidance for calculating compensation for individual loan originators is no longer necessary. Accordingly, the Bureau is deleting portions of comments 32(b)(1)(ii)–2.ii and –3, and, the entirety of comment 32(b)(1)(ii)–4.

Compensation paid by creditors to mortgage brokers. In response to the Board's 2011 ATR Proposal, many industry commenters urged the Bureau to exclude loan originator compensation from points and fees altogether. *See* 78 FR 6433 (Jan. 30, 2013). Among other things, industry commenters had argued that compensation paid to loan originators already is included in the cost of the loan and has little, if any bearing on a consumer's ability to repay a mortgage loan. They also argued that other statutory provisions and rules already provide adequate protection from abusive loan originator compensation practices and that it therefore is unnecessary to include loan originator compensation in points and fees. Finally, they argued that including loan originator compensation in points and fees would cause many loans to exceed the qualified mortgage points and fees limits, which would result in an increase in the cost of credit and diminished access to credit.

In the 2013 ATR Final Rule, the Bureau acknowledged the concerns about including loan originator compensation in points and fees. However, the Bureau noted that, in light of the express statutory language and Congress's evident concern with increasing consumer protections in connection with loan originator compensation practices, the Bureau did not believe it appropriate to use its exception authority to exclude loan originator compensation entirely from points and fees. In response to the 2013 ATR Proposed Rule, many industry commenters, including mortgage brokers and their representatives and some creditors and their representatives, again urged the Bureau to exclude loan originator compensation from points and fees altogether (or to at least exclude from points and fees all compensation paid by creditors to loan originators). Repeating many of the same arguments made in response to the Board's 2011 ATR Proposal, these commenters argued that loan originator compensation already is included in the cost of the loan and has little or no effect on consumers' ability to repay the loan. They claimed that other protections adopted by the Bureau and the Board adequately protect consumers against harmful loan originator compensation practices and that it therefore is unnecessary to include loan originator compensation in points and fees. Finally, they argued that including loan originator compensation in points and fees would cause many loans to exceed the qualified mortgage points and fees cap or the high-cost mortgage threshold and that, as a result, many loans would not be made, including in particular smaller loans.

The Bureau does not believe that it is consistent with the standards for its use of exception and adjustment authority to exclude from points and fees compensation paid by creditors to loan originators that are not employees of creditors. As noted above, in excluding from points and fees compensation paid by creditors to their loan originator employees, the Bureau invoked its exception and adjustment authority to facilitate compliance and, generally speaking, to meet purposes of ensuring that credit is available to consumers on reasonably repayable terms. These factors do not support excluding compensation paid by creditors to loan originators not employed by creditors. The compliance burden of calculating compensation paid by creditors to loan originators other than their own employees is minimal and does not provide a basis for exclusion based on a rationale related to facilitating compliance. As noted above, this calculation is straightforward for compensation paid by creditors to mortgage brokers: For each transaction, creditors typically pay a commission to mortgage brokers pursuant to a pre-existing contract between the creditor and the broker, and that commission is known at the time the interest rate is set.[130] Moreover, as discussed below, the Bureau believes that there remain some risks of consumer injury from business models in which mortgage brokers attempt to steer consumers to more costly transactions. Including in points and fees compensation paid by creditors to mortgage brokers should help reduce those risks. Accordingly, the Bureau declines to use its exception authority to exclude such compensation from points and fees.

The Bureau also does not believe it is appropriate to use its exception authority to exclude loan originator compensation payments from creditors to mortgage brokers in certain types of transactions. As noted above, one industry commenter urged the Bureau to consider whether compensation paid by creditors to mortgage brokers should be included in points and fees only in subprime transactions. The commenter did not provide data or other evidence to support this approach. In addition, subprime transactions already have less flexibility than prime transactions under the points and fees limits because bona fide discount points may not excluded from points and fees for transactions with interest rates greater than 2 percentage points above APOR, *see* § 1026.32(b)(1)(i)(E) and (F), and the Bureau is concerned about widening the disparity in treatment under the points and fees limits. Accordingly, the Bureau does not believe it is appropriate to use its exception authority to create different requirements for loan originator compensation in the prime and subprime markets. Another commenter requested that, to avoid impairing affordable lending programs offered by nonprofit organizations, the Bureau exclude such payments when the creditor absorbs the costs of the payments and does not pass along the costs to consumers.[131] The Bureau believes it would be difficult, if not impossible, to determine when a creditor was in fact not passing along loan origination costs to consumers and that any exemption, even if well-intentioned, could be susceptible to abuse.

In the 2013 ATR Proposed Rule, the Bureau proposed two alternatives—an ''additive'' approach and a ''netting'' approach— for calculating compensation. As discussed above, proposed alternative 1 of comment 32(b)(1)(ii)–5.iii would have adopted an additive approach in which loan originator compensation would have been included in points and fees in addition to any charges paid by the consumer to the creditor. Proposed alternative 2 of comment 32(b)(1)(ii)–5.iii would have permitted creditors to net origination charges against loan originator compensation to calculate the

[130] As discussed above, the compliance burden of calculating compensation paid by creditors to their own loan officers is substantial and offsets the limited potential consumer protection benefits of including such compensation in points and fees.

[131] As discussed below, the Bureau is adopting § 1026.43(a)(3)(v), which exempts certain creditors, including certain nonprofit creditors, from the ability-to-repay requirements.

amount of loan originator compensation that is included in points and fees. As discussed above, a creditor's payments to a loan originator may be funded by up-front charges to the consumer, through the interest rate, or through some combination. The up-front charges to the consumer would be captured in points and fees, but compensation funded through the interest rate would not be captured. Thus, when a consumer pays up-front charges, it is not clear whether a creditor's payments to a loan originator are captured in such points and fees.[132]

As noted above, the Bureau reads the statutory language as requiring that loan originator compensation be included in points and fees in addition to any other items that are included in points and fees, even if the loan originator compensation may have been funded through charges that already are included in points and fees. Moreover the Bureau reads the statutory provision on compensation as meaning that compensation is added as it flows downstream from one party to another so that it is counted each time that it reached a loan originator, whatever its previous source. After carefully considering the comments, the Bureau has determined that, for calculating compensation paid by creditors to mortgage brokers, it is not necessary or proper to revise the additive approach prescribed by the statute and adopted in the 2013 ATR Final Rule.

For creditor payments to loan originators not employed by creditors, calculating loan originator compensation under an additive approach does not impose a significant compliance burden. As noted above, this calculation is straightforward for compensation paid by creditors to mortgage brokers: For each transaction, creditors typically pay a commission to mortgage brokers pursuant to a pre-existing contract between the creditor and the broker, and that commission is known at the time the interest rate is set.

For transactions in the wholesale channel, brokers and creditors can obviate double counting concerns by having consumers pay brokers directly.[133] Under new comment 32(b)(1)(ii)–5.i, the consumer's payment to the mortgage broker would be included in points and fees only one time. For example, assume a consumer is seeking a $100,000 loan and wants to pay $2,500 in up-front charges at closing rather than paying those costs through a higher interest rate. The transaction is being originated through a mortgage broker firm, which charges $1,500. Under an additive approach, if the consumer pays $2,500 in origination charges to the creditor and the creditor pays $1,500 to the mortgage broker firm, the points and fees would be $4,000 and the loan could not be a qualified mortgage. However, if the consumer pays $1,500 directly to the mortgage broker firm and then pays $1,000 in origination charges to the creditor, then the points and fees would be $2,500 and would not prevent the loan from being a qualified mortgage. Moreover, if the consumer pays the mortgage broker directly, then the creditor would no longer be responsible for the cost of compensating the mortgage broker; as a result, the interest rate should be the same whether the consumer pays $1,500 to the mortgage broker and $1,000 to the creditor or the consumer pays $2,500 to the creditor and the creditor pays $1,500 to the mortgage broker. In light of the options that direct consumer payments provide in the wholesale channel, the Bureau believes that affordable credit will continue to be available in connection with wholesale loans and that use of adjustment authorities to achieve statutory purposes is not necessary.

The Bureau is concerned that, as noted by the FDIC and HUD, by the OCC, and by some consumer advocate commenters, a netting rule in the wholesale channel could create incentives for mortgage brokers and creditors to structure transactions so that loan originator compensation is paid by the creditor to the mortgage broker, rather than by the consumer to the mortgage broker. Under a netting rule, creditors could impose origination charges on the consumer and net those charges against the compensation the creditor pays the mortgage broker when calculating points and fees. By contrast, in a transaction in which the consumer pays the mortgage broker directly, the consumer's payment to the mortgage broker would be included in points and fees in addition to any origination charges imposed by the creditor. Thus, a netting rule likely would provide creditors with a greater ability to charge up-front fees and still remain under the points and fees limits.[134] The Bureau believes it would be anomalous to treat wholesale transactions differently for purposes of the qualified mortgage and high-cost mortgage points and fees limits simply because in one transaction the consumer paid compensation directly to the mortgage broker and in another transaction the consumer paid the compensation indirectly. Such an anomaly would actually disserve the broad purposes of TILA to inform consumers because in the transaction that would be favored (*i.e.,* the transaction in which the broker's commission is bundled in the fees paid to the creditor or in the interest rate) the costs would be less transparent than in the disfavored transaction (*i.e.,* the transaction in which the consumer paid the compensation directly to the broker).

Finally, an additive approach would place some additional limits on the ability of mortgage brokers to obtain high compensation for loans that are more costly to consumers. As noted above, consumer advocates have identified two ways in which mortgage brokers potentially could extract high compensation for delivering loans that are more costly to consumers (and possibly more profitable for creditors) would not appear to violate the prohibitions on steering and compensating loan originators based on loan terms. First, mortgage brokers could specialize in providing creditors with loans that are more costly to consumers in exchange for high compensation, so long as that compensation does not vary based on the terms of individual loans.

Second, mortgage brokers could do business with a mix of creditors, some offering more costly loans (and paying high compensation to mortgage brokers) and some offering loans with more favorable terms (and paying lower compensation to brokers). Mortgage

[132] It is doubtful that Congress contemplated this issue because, as noted above, absent the Bureau's use of exception authority, TILA section 129B(c)(2)(B)(ii) would have prohibited a creditor from imposing origination fees or charges if the creditor were compensating a loan originator.

[133] The Bureau does not believe that the potential double counting of loan originator compensation and origination charges could be adequately addressed by permitting a netting approach in combination with more detailed disclosures to consumers. The Bureau notes that, because money is fungible, creditors could adjust their accounting so that they could disclose that they are recovering loan originator compensation through up-front charges and other origination costs through the interest rate. Thus, this disclosure-based approach would permit creditors to reduce the amount of loan originator compensation they include in points and fees without changing the amount of up-front fees or the interest rate they charge. Moreover, given the complex interaction between loan originator compensation, up-front charges, and the interest rate, the Bureau has concerns that consumers would not understand the disclosures.

[134] As consumer advocates noted in their comments, mortgage brokers historically have defended arrangements in which creditors pay compensation to mortgage brokers by arguing that this approach permits consumers to obtain mortgage loans when they do not have sufficient funds to compensate mortgage brokers directly. *See Nat'l Assoc. of Mortgage Brokers v. Fed. Reserve Bd.,* 773 F.Supp. 2d 151, 158 (D.D.C 2011). This rationale for creditors' paying compensation to mortgage brokers has little if any force if the consumer is paying up-front charges to the creditor.

brokers could attempt to steer borrowers that are less sophisticated and less likely to shop for better terms to the creditors with more costly loans, and they potentially could evade the anti-steering prohibition by offering quotes from at least three such creditors.[135] An additive approach likely would reduce the potential consumer injury by limiting the ability of creditors to impose high up-front charges and pay high loan originator compensation, unless creditors are willing to exceed the qualified mortgage points and fees limits and, potentially, to bear the burden of originating high-cost mortgages under HOEPA.[136]

The Bureau recognizes that an additive approach makes it more difficult for creditors to impose up-front charges and still remain under the qualified mortgage points and fees limits and the high-cost mortgage threshold. Commenters provided limited data regarding the magnitude of the effects of an additive approach. Nevertheless, even in transactions in which a mortgage broker's compensation is two percentage points of the loan amount—which the Bureau understands to be at the high end of mortgage broker commissions—the creditor would still be able to charge up to one point in up-front charges that would count toward the qualified mortgage points and fees limits. As noted above, the creditor may reduce the costs it needs to recover from origination charges or through the interest rate by having the consumer pay the mortgage broker directly. In addition, creditors in the wholesale channel that prefer to originate only qualified mortgages in many cases will have the flexibility to recover more of their origination costs through the interest rate to ensure that their transactions remain below the points and fees limits.[137]

For the reasons discussed above, the Bureau believes that it is neither necessary nor appropriate to deviate from the additive approach prescribed by the statute and adopted in the 2013 ATR Final Rule to calculate compensation paid by creditors to mortgage brokers. The Bureau believes that affordable credit will continue to be available in connection with loans in the wholesale channel and that use of adjustment authorities to achieve statutory purposes is not necessary and proper. As noted above, the Bureau believes that, to the extent that the additive approach limits the ability of mortgage brokers to steer consumers toward more costly loans, the additive approach is consistent with the statutory purposes. Accordingly, the Bureau concludes that it should not exercise its exception authority to alter the additive approach prescribed by the statute. Accordingly, as adopted by this final rule, comment 32(b)(1)(ii)–4.iii clarifies that, for loan originators that are not employees of the creditor, (*i.e.,* mortgage brokers, as defined in § 1026.36(a)(2)) loan originator compensation is included in points and fees in addition to any origination charges that are paid by the consumer to the creditor.

As noted above, the term ''mortgage broker'' is defined in § 1026.36(a)(2) to mean any loan originator other than an employee of a creditor. The Bureau believes that the additive approach is appropriate for all mortgage brokers, including persons whose primary business is not originating mortgage loans but who nevertheless qualify as a ''mortgage broker'' under § 1026.36(a)(2). In general, calculating compensation paid by a consumer or creditor to such persons for loan origination activities should be straightforward and would impose little compliance burden. However, as discussed below, the Bureau intends to provide additional guidance for calculating loan originator compensation for manufactured home transactions.

Loan originator compensation for open-end credit plans. For the high-cost mortgage points and fees threshold, the 2013 HOEPA Final Rule applied the same requirements for including loan originator compensation in points and fees in open-end credit plans as for closed-end credit transactions. In the 2013 ATR Proposed Rule, the Bureau solicited comment about whether different or additional guidance is appropriate for calculating loan originator compensation for open-end credit plans. The Bureau received few comments that addressed open-end credit plans, and they did not advocate for different or additional guidance. Accordingly, the Bureau believes that it is appropriate to continue to apply the same requirements for calculating loan originator compensation for points and fees in closed-end credit transactions and open-end credit plans. The Bureau is therefore revising § 1026.32(b)(2)(ii), which addresses loan originator compensation for open-end credit plans, to incorporate the same exclusions from points and fees as those discussed above for closed-end credit transactions in § 1026.32(b)(1)(ii). The Bureau is not adopting additional guidance for open-end credit plans.

Calculation of loan originator compensation for manufactured home transactions. As noted above, several industry and nonprofit commenters requested clarification of what compensation must be included in points and fees in connection with transactions involving manufactured homes. They requested additional guidance on what activities would cause a manufactured home retailer and its employees to qualify as loan originators. The 2013 Loan Originator Final Rule had provided additional guidance on what activities would cause such a retailer and its employees to qualify as loan originators in light of language in the Dodd-Frank Act creating an exception from the definition of loan originator for employees of manufactured home retailers performing certain limited activities. *See* § 1026.36(a)(1)(i)(B) and comments 36(a)-1.i.A and 36(a)-4. The commenters nevertheless argued that it remains unclear what activities a retailer and its employees could engage in without qualifying as loan originators and causing their compensation to be included in points and fees. Industry commenters also noted that, because a creditor has limited knowledge of and control over the activities of a retailer and its employees, it would be difficult for a creditor to know whether a retailer and its employees had engaged in activities that would require their compensation to be included in points and fees. Industry commenters therefore urged the Bureau to adopt a bright-line rule that would exclude from points and fees compensation paid to manufactured home retailers and their employees. They also requested that the Bureau clarify that, in any event, compensation received by the manufactured home retailer or its employee for the sale of the home should not be counted as loan

[135] Competitive market pressures and the difficulties of specializing in (or at least identifying and steering) vulnerable consumers may constrain mortgage brokers' ability to exploit gaps in the regulatory structure. Nevertheless, the Bureau is concerned about the potential for consumer injury, particularly for consumers who are less sophisticated or less likely to shop for competitive terms.

[136] The Bureau recognizes that an additive approach would not preclude creditors from paying mortgage brokers above-market compensation (up to the points and fees limits) and recovering the costs of compensating the mortgage brokers and other costs through an above-market interest rate. However, as consumer advocates noted in their comments, consumers may shop more effectively when comparing a single variable, such as the interest rate.

[137] Moreover, to the extent that consumers prefer to pay up-front charges to reduce the interest rate, creditors may be able to exclude as many as two bona fide discount points under § 1026.32(b)(1)(i)(E) or (F).

originator compensation and included in points and fees.

The Bureau does not believe it is appropriate to exclude compensation that is paid to a manufactured home retailer for loan origination activities. In such circumstances, the retailer is functioning as a mortgage broker and compensation for the retailer's loan origination activities should be captured in points and fees. The Bureau recognizes, however, that it may be difficult for a creditor to ascertain whether a retailer engages in loan origination activities and, if so, what compensation that retailer receives for those activities, at least when such compensation was not paid directly by the creditor itself. Accordingly, the Bureau intends to propose additional guidance on these issues prior to the effective date of the 2013 ATR Final Rule to facilitate compliance.

With respect to employees of manufactured home retailers, the Bureau believes that, in most circumstances, new § 1026.32(b)(1)(ii)(B) will make it unnecessary for creditors to determine whether employees of retailers have engaged in loan origination activities that would cause them to qualify as loan originators. As discussed above, § 1026.32(b)(1)(ii)(B) excludes compensation paid by mortgage brokers to their loan originator employees. In the usual case, when an employee of a retailer would qualify as a loan originator, the retailer would qualify as a mortgage broker. If the retailer is a mortgage broker, any compensation paid by the retailer to the employee would be excluded from points and fees under § 1026.32(b)(1)(ii)(B). Nevertheless, as part of its proposal to provide additional guidance as noted above, the Bureau intends to request comment on whether additional guidance is necessary for calculating loan originator compensation for employees of manufactured home retailers.

Other issues related to points and fees. As noted above, many commenters requested that the Bureau reconsider whether certain items should be included in points and fees. In particular, many commenters urged that real-estate related charges paid to affiliates and up-front charges imposed by creditors on consumers to recover the costs of LLPAs should not be included in points and fees. Commenters also asked the Bureau to permit the creditor to exclude more than two bona fide discount points from points and fees. The Bureau is not reconsidering its decision that, as provided in the statute, real-estate related charges paid to affiliates of the creditor are included in points and fees. The Bureau also declines to reconsider its decision that, where a creditor recovers the costs of LLPAs through up-front charges to the consumer, those charges are included in points and fees. Finally, the Bureau is not reconsidering its decision that, as provided in the statute, creditors may exclude no more than two bona fide discount points from points and fees.

Many individual mortgage brokers and a trade group representing mortgage brokers urged the Bureau to reconsider certain restrictions on loan originator compensation in § 1026.36(d)(1) and (2), arguing that these restrictions are unnecessary because the points and fees limits for qualified mortgages effectively cap loan origination compensation at 3 percent of the loan amount.[138] The 2013 Loan Originator Final Rule clarified and expanded § 1026.36(d)(1) and (2), and the Bureau declines to revisit those provisions in this rulemaking.

Section 1026.35 Prohibited Acts or Practices in Connection With Higher-Priced Mortgage Loans

35(b) Escrow Accounts

35(b)(2) Exemptions

35(b)(2)(iii)

As discussed further below, the Bureau proposed § 1026.43(e)(5) to create a new type of qualified mortgage for certain portfolio loans originated and held by small creditors. The Bureau proposed to adopt the same parameters defining small creditor for purposes of the new category of qualified mortgage as it had used in implementing provisions of the Dodd-Frank Act that allow certain balloon loans to receive qualified mortgage status and an exemption from the requirement to maintain an escrow accounts for certain higher priced mortgage loans where such loans are made by small creditors operating predominantly in rural or underserved areas. The size thresholds for purposes of the rural balloon and escrow provisions are set forth in § 1026.35(b)(2)(iii), as adopted by the 2013 Escrows Final Rule, which provides that an escrow account need not be established in connection with a mortgage if the creditor, within applicable time periods, annually extends more than 50 percent of its covered first-lien transactions on properties that are located in rural or underserved counties, originates (with its affiliates) 500 or fewer first-lien covered transactions per year, and has total assets of less than $2 billion (adjusted annually for inflation), in addition to other escrow account limitations.

The Bureau did not propose to make any specific amendments to the escrows provision in § 1026.35(b)(2), but indicated that if the provisions creating a new type of small creditor portfolio qualified mortgage in proposed § 1026.43(e)(5) were adopted with changes inconsistent with § 1026.35(b)(2), the Bureau would consider and might adopt parallel amendments to § 1026.35(b)(2) to keep these sections of the regulation consistent.

The Bureau solicited comment on the advantages and disadvantages of maintaining consistency between § 1026.35(b)(2) and § 1026.43(e)(5). Commenters did not specifically address the importance of consistency. However, several small creditors and a small creditor trade group raised concerns regarding the cost and burden associated with the escrow requirements and urged the Bureau to expand or adopt exceptions to those requirements. For example, commenters suggested broadening the § 1026.35(b)(2)(iii) exemption and exempting home improvement loans and loans secured by mobile homes.

As discussed below in the section-by-section analysis of § 1026.43(e)(5), the Bureau is adopting § 1026.43(e)(5) consistent with existing § 1026.35(b)(2) with regard to the asset size and annual loan origination thresholds defining a small creditor. The Bureau did not propose and did not solicit comment regarding other amendments to the escrow provisions in § 1026.35(b)(2). The Bureau therefore is not reconsidering the issues raised by commenters at this time and is not adopting any changes to § 1026.35(b)(2) in this rulemaking.

Section 1026.43 Minimum Standards for Transactions Secured by a Dwelling

43(a) Scope

43(a)(3)

Background

Section 129C(a)(1) of TILA, as added by section 1411 of the Dodd-Frank Act, states that, in accordance with regulations prescribed by the Bureau, no creditor may make a residential mortgage loan unless the creditor makes a reasonable and good faith determination based on verified and documented information that, at the time the loan is consummated, the consumer has a reasonable ability to

[138] The Bureau notes that the general 3 percent points and fees limit applies only to qualified mortgages and would not restrict the loan originator compensation paid to mortgage brokers in mortgage transactions that are not qualified mortgages.

repay the loan, according to its terms, and all applicable taxes, insurance (including mortgage guarantee insurance), and assessments. Section 1401 of the Dodd-Frank Act adds new TILA section 103(cc)(5), which defines ''residential mortgage loan'' to mean, with some exceptions, any consumer credit transaction secured by a mortgage, deed of trust, or other equivalent consensual security interest on ''a dwelling or on residential real property that includes a dwelling.'' TILA section 103(v) defines ''dwelling'' to mean a residential structure or mobile home which contains one- to four-family housing units, or individual units of condominiums or cooperatives. Thus, a ''residential mortgage loan'' generally includes all mortgage loans, except mortgage loans secured by a structure with more than four residential units. However, TILA section 103(cc)(5) specifically excludes from the term ''residential mortgage loan'' an open-end credit plan and an extension of credit secured by an interest in a timeshare plan, for purposes of the ability-to-repay requirements under TILA section 129C as well as provisions concerning prepayment penalties and other restrictions. In addition, TILA section 129C(a)(8) exempts reverse mortgages and temporary or ''bridge'' loans with a term of 12 months or less from the ability-to-repay requirements. Thus, taken together, the ability-to-repay requirements of TILA section 129C(a) apply to all closed-end mortgage loans secured by a one- to four-unit dwelling, except loans secured by a consumer's interest in a timeshare plan, reverse mortgages, or temporary or ''bridge'' loans with a term of 12 months or less.

The Bureau's 2013 ATR Final Rule adopted provisions on scope that are substantially similar to the statute, which included modifications to conform to the terminology of Regulation Z. However, feedback provided to the Bureau suggested that the ability-to-repay requirements would impose an unsustainable burden on certain creditors, such as housing finance agencies (HFAs) and certain nonprofit organizations, offering mortgage loan programs for low- to moderate-income (LMI) consumers. The Bureau was concerned that the ability-to-repay requirements adopted in the 2013 ATR Final Rule would undermine or frustrate application of the uniquely tailored underwriting requirements employed by these creditors and programs, and would require a significant diversion of resources to compliance, thereby significantly reducing access to credit. The Bureau was also concerned that some of these creditors would not have the resources to implement and comply with the ability-to-repay requirements, and may have ceased or severely limited extending credit to low- to moderate-income consumers, which would result in the denial of responsible, affordable mortgage credit. In addition, the Bureau was concerned that the ability-to-repay requirements may have frustrated the purposes of certain homeownership stabilization and foreclosure prevention programs, such as Hardest-Hit-Fund (HHF) programs and the Home Affordable Refinance Program (HARP). Accordingly, the Bureau proposed several exemptions intended to ensure that responsible, affordable mortgage credit remained available for LMI and financially distressed consumers.

43(a)(3)(iv)

The Bureau's Proposal

As discussed above, neither TILA nor Regulation Z provide an exemption to the ability-to-repay requirements for extensions of credit made pursuant to a program administered by a Housing Finance Agency (HFA), as defined under 24 CFR 266.5. However, the Bureau was concerned that the ability-to-repay requirements may unnecessarily impose additional requirements onto the underwriting requirements of HFA programs and impede access to credit available under these programs. The Bureau was especially concerned that the costs of implementing and complying with the requirements of § 1026.43(c) through (f) would endanger the viability and effectiveness of these programs. The Bureau was concerned that the burden could prompt some HFAs to severely curtail their programs and some private creditors that partner with HFAs to cease participation in such programs, both of which could reduce mortgage credit available to LMI consumers. The Bureau was also concerned that the ability-to-repay requirements may affect the ability of HFAs to apply customized underwriting criteria or offer customized credit products that are designed to meet the needs of LMI consumers while promoting long-term housing stability.

Based on these concerns and to obtain additional information regarding these potential effects, the Bureau proposed an exemption and solicited feedback on several issues. Proposed § 1026.43(a)(3)(iv) would have provided an exemption to the ability-to-repay requirements for credit extended pursuant to a program administered by an HFA. The Bureau solicited comment on every aspect of this approach. In particular, the Bureau sought comment on the premise that the ability-to-repay requirements could impose significant implementation and compliance burdens on HFA programs even if credit extended under the HFA programs were granted a presumption of compliance as qualified mortgages. The Bureau also sought comment on whether HFAs have sufficiently rigorous underwriting standards and monitoring processes to protect the interests of consumers in the absence of TILA's ability-to-repay requirements. The Bureau also requested data related to the delinquency, default, and foreclosure rates of consumers participating in these programs. In addition, the Bureau solicited feedback regarding whether such an exemption could harm consumers, such as by denying consumers the ability to pursue claims arising under violations of § 1026.43(c) through (f) against creditors extending credit in connection with these programs. Finally, the Bureau also requested feedback on any alternative approaches that would preserve the availability of credit under HFA programs while ensuring that consumers receive mortgage loans that reasonably reflect consumers' ability to repay.

Comments Received

In response to the proposed rule, some commenters completely opposed the proposed exemption from the ability-to-repay requirements for extensions of credit made pursuant to programs administered by HFAs. These commenters generally argued that the rules should apply equally to all creditors. These commenters contended that granting exemptions to certain creditors would create market distortions and steer consumers towards certain creditors, thereby reducing consumer choice and ability to shop. Other commenters suggested alternative modifications to address HFA programs. One industry commenter favored creating special ability-to-repay requirements tailored to the unique underwriting characteristics of LMI consumers. Another industry commenter supported some type of exemption from the ability-to-repay requirements but advocated for conditions or the provision of authority to HFAs to impose their own ability-to-repay standards, as various Federal agencies (the Department of Housing and Urban Development, the Department of Veterans Affairs, and the Department of Agriculture), are authorized to do. The majority of

industry and consumer group commenters, however, asserted that the proposed exemption to the ability-to-repay requirements for credit extended pursuant to a program administered by an HFA is necessary because these programs meet the customized needs of LMI consumers who are creditworthy but may not otherwise qualify for mortgage credit under the Bureau's ability-to-repay requirements.

The latter group of commenters generally supported the Bureau's goal of preserving access to affordable credit for LMI consumers and favored the Bureau's proposal to exempt community-focused lending programs from the ATR requirements altogether. These commenters contended that HFA loan products balance access to residential mortgage credit for LMI consumers with a focus on the consumer's ability to repay. Consumer group commenters argued that HFA lending programs typically offer low-cost mortgage products, require full documentation of income and demonstrated ability to repay, and often include extensive financial counseling with the consumer. Commenters argued that HFA homeowner assistance programs are tailored to the credit characteristics of LMI consumers that HFAs serve and noted that these organizations only extend credit after conducting their own lengthy and thorough analysis of an applicant's ability to repay, which often account for nontraditional underwriting criteria, income sources that do not fall within typical mortgage underwriting criteria, extenuating circumstances, and other subjective factors that are indicative of responsible homeownership and ability to repay. An industry commenter noted that, for first-time homebuyer lending, HFAs use a combination of low-cost financing and traditional fixed-rate, long-term products; flexible, but prudent, underwriting with careful credit evaluation; diligent loan documentation and income verification; down payment and closing cost assistance; homeownership counseling; and proactive counseling and servicing. This commenter stated that many HFAs elaborate beyond the underwriting standards of Federal government agencies, such as FHA, USDA, or RHS loans, and that HFAs also oversee creditors involved in these programs carefully by ensuring the HFA's strict underwriting standards and lending requirements are followed. Comments provided to the Bureau state that a New York State HFA considers the consumer's entire credit history rather than consider only a consumer's credit score, which allows it to help those consumers who may have a lower credit score due to a prior financial hardship. Whereas creditors do not need to engage in separate verification where a consumer's application lists a debt that is not apparent from the consumer's credit report pursuant to § 1026.43(c), comments provided to the Bureau also state that the Pennsylvania Housing Finance Agency's underwriting standards require that the creditor provide a separate verification of that obligation, indicating the current balance, the monthly payment, and the payment history of the account.

Commenters also provided data related to the relative performance of HFA loans as further justification to support the proposed exemption from the ability-to-repay requirements for extensions of credit made pursuant to a program administered by a HFA. Although comprehensive data for HFA loan performance are not available, commenters reported that the delinquency, default, and foreclosure statistics for consumers who receive mortgage loans from HFA programs are generally lower than for those of the general populace, which demonstrates that HFA programs ensure that consumers are extended credit on reasonably repayable terms.[139] Commenters reported that a limited review of HFA loan data conducted by Fannie Mae in 2011 found that HFA-financed loans performed significantly better than other Fannie Mae affordable housing loans. Also, comments cited a 2011 National Council of State Housing Agencies (NCSHA) study of HFA-financed and non-HFA-financed loans insured by FHA that found that, in a large majority of States, HFA-financed loans had lower long-term delinquency and foreclosure rates than non-HFA loans.

A number of commenters argued that, in the absence of an exemption, HFA homeowner assistance programs would not be able to continue to meet the needs of LMI consumers or distressed borrowers as intended. Commenters generally stated that requiring HFAs to comply with the ability-to-repay requirements would be unduly burdensome and would have a negative impact on their ability to offer consumers loan products that fit their unique needs, thereby endangering the viability and effectiveness of these programs. Commenters also argued that HFAs, which are governmental entities chartered by either a State or a municipality and are taxpayer-supported, may not have sufficient resources to implement and comply with the ability-to-repay requirements. According to commenters, some HFAs may respond to the burden by severely curtailing the credit offered under these programs and others may divert resources from lending to compliance, which may also reduce access to credit for LMI consumers.

Commenters noted that, because most HFAs operate in partnership with private creditors who participate voluntarily in HFA programs, the Bureau's proposed HFA exemption would help encourage eligible creditors to continue making loans that might not otherwise be originated due to constraints under, or concerns about, the Bureau's ability-to-repay requirements. Commenters argued that the ability-to-repay requirements would impose significant implementation and compliance burdens on participating private creditors, and this would likely discourage creditors from participating in HFA programs and would result in the denial of mortgage credit to LMI consumers.

A number of industry commenters argued that the proposed exemption from the ability-to-repay requirements is in the best interests of consumers and the nation as a whole, as the exemption will allow homeowners to remain in their homes and help stabilize communities that were harmed by the mortgage crisis and limit the degree to which future LMI consumers have difficulty obtaining access to credit. Creditors also generally supported clarifying that the exemption applies regardless of whether the credit is extended directly by an HFA to the

[139] For example, as of September 30, 2012, just 3.7 percent of SONYMA's single-family borrowers were 60 or more days delinquent, compared with 10.9 percent of all borrowers. Data from the Pennsylvania Housing Finance Agency show that for the third quarter of 2012, its conventional loans had 90-plus day delinquency and foreclosure rates of 2.98 percent and .99 percent, respectively, which are well below the equivalent rates for all conventional loans in the State of Pennsylvania. Data from the Massachusetts Housing Partnership's SoftSecond Program show that the foreclosure rate for program loans is substantially lower than the rate for prime loans in the State of Massachusetts (0.87 percent for SoftSecond loans as compared to 1.72 percent for prime loans). FHA-insured loans purchased by the Connecticut Housing Finance Agency have lower foreclosure rates than comparable FHA loans in the northeast, and loans financed by the Delaware State Housing Authority and serviced by U.S. Bank have a 60 days or more delinquency rate of just over 2 percent, compared with a national 60 days or more rate of 8.3 percent. Finally, Virginia Housing Development Authority loan foreclosure rates on FHA and conventional loans both fall under 1 percent. This is 3.2 percentage points under the national FHA foreclosure rate and 2.5 percentage points lower than the national foreclosure rate for conventional loans in New York State, according to the Mortgage Bankers Association. Prior to the recent mortgage crisis, SONYMA's 60-plus day default rate had never exceeded 2 percent.

consumer or through an intermediary that is operating pursuant to a program administered by an HFA, and to include all HFA programs regardless of structure (*e.g.,* mortgage revenue bonds or mortgage credit certificates).

The Final Rule

Based on these comments and considerations, the Bureau believes that it is appropriate to exempt credit extended pursuant to an HFA program from the ability-to-repay requirements. The comments received confirm that HFA programs generally employ underwriting requirements that are uniquely tailored to meet the needs of LMI consumers, such that applying the more generalized statutory ability-to-repay requirements would provide little or no net benefit to consumers and instead could be unnecessarily burdensome by diverting the focus of HFAs and their private creditor partners from mission activities to managing compliance and legal risk from two overlapping sets of underwriting requirements. The Bureau is concerned that absent an exemption, this diversion of resources would significantly reduce access to responsible mortgage credit for many LMI borrowers.

As discussed above in part II.A, many HFAs expand on the underwriting standards of GSEs or Federal government agencies by applying even stricter underwriting standards than these guidelines, such as requiring mandatory counseling for all first-time homebuyers and strong loan servicing. As HFAs extend credit to promote long-term housing stability, rather than for profit, HFAs generally extend credit after performing a complex and lengthy analysis of a consumer's ability to repay. As also discussed above in part II.A, the Bureau finds that, as compared to traditional underwriting criteria, under which LMI borrowers may be less likely to qualify for credit, the underwriting standards of some HFAs allow greater weight for (and sometimes require) the consideration of nontraditional underwriting elements, extenuating circumstances, and other subjective compensating factors that are indicative of responsible homeownership. The Bureau notes, however, that HFAs do conduct regular and careful oversight of their lenders, helping ensure that they follow the HFAs' strict underwriting standards.

The Bureau is concerned that HFAs, which are governmental entities and taxpayer-supported, may not have sufficient resources to implement and comply with the ability-to-repay requirements, or that the additional compliance burdens would at least significantly reduce the resources available to HFAs for the purpose of providing homeowner assistance. As discussed above in part II.A, many of the State and Federal programs that HFAs administer do not provide administrative funds; others provide limited administrative funds. Most HFAs operate independently and do not receive State operating funds. Consequently, HFAs may not have enough resources to increase compliance efforts without negatively impacting their missions. In the absence of an exemption from the ability-to-repay requirements, HFAs would have to dedicate substantially more time and resources to ensure their programs and lending partners are in compliance.

Moreover, because many HFAs must conduct their programs through partnerships with private creditors, the Bureau is concerned that absent an exemption private creditor volunteers would determine that complying with both the ability-to-repay requirements and the specialized HFA program requirements is too burdensome or the liability risks too great. For example, needing to comply with both the HFA underwriting requirements that often account for (and sometimes require the consideration of) nontraditional underwriting criteria, extenuating circumstances, and compensating factors, as discussed above in part II.A, and the ability-to-repay requirements may cause some private creditors to cease participation in such programs. This too would reduce access to mortgage credit to LMI consumers.

With respect to the comment suggesting that a better approach would be to allow HFAs to establish their own ability-to-repay and qualified mortgage guidelines, the Bureau notes that Congress has the authority to determine which agencies and programs have the authority under TILA to prescribe rules related to the ability-to-repay requirements or the definition of qualified mortgage. The Bureau is mindful that Congress has not authorized HFAs to prescribe rules related to the ability-to-repay requirements or the definition of qualified mortgage.

Regarding the comment favoring the creation of special ability-to-repay requirements tailored to the unique underwriting characteristics of LMI consumers, the Bureau does not believe it is appropriate to establish alternative conditions. HFA programs have strong but flexible ability-to-repay requirements tailored to the unique needs and credit characteristics of the LMI consumers they serve. The Bureau is concerned that imposing uniform alternative requirements by regulation would curtail this flexibility and ultimately reduce access to responsible and affordable credit for this population.

No commenters addressed whether credit extended pursuant to a program administered by an HFA should be granted a presumption of compliance as qualified mortgages, and, if so, under what conditions. However, the Bureau does not believe that extending qualified mortgage status to these loans would be as effective in addressing the concerns raised above as an exemption. Even if credit extended under the HFA programs were granted a presumption of compliance as qualified mortgages, HFA programs could be impacted by significant implementation and compliance burdens. Furthermore, as discussed above, many loans extended under these programs would not appear to satisfy the qualified mortgage standards under § 1026.43(e)(2). Thus, a creditor extending such a mortgage loan would still be required to comply with the ability-to-repay requirements of § 1026.43(c) and the potential liability of noncompliance would cease or severely curtail mortgage lending.

The Bureau received a number of comments completely opposed to the proposed exemptions from the ability-to-repay requirements on the grounds that the rules should apply equally to all creditors. However, pursuant to section 105(a) of TILA, the Bureau generally may prescribe regulations that provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary or proper to effectuate the purposes of TILA, among other things. In addition, pursuant to TILA section 105(f) the Bureau may exempt by regulation from all or part of this title all or any class of transactions for which in the determination of the Bureau coverage does not provide a meaningful benefit to consumers in the form of useful information or protection, if certain conditions specified in that section are met. For the reasons discussed in each relevant section, the Bureau believes that the exemptions adopted in this final rule are necessary and proper to effectuate the purposes of TILA, which include purposes of section 129C, by ensuring that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay. Furthermore, without the exemptions the Bureau believes that consumers in these demographics are at risk of being denied access to the responsible, affordable credit offered under these programs, which is contrary to the purposes of TILA.

Accordingly, the Bureau believes that the proposed exemption for credit made pursuant to programs administered by an HFA is appropriate under the circumstances. The Bureau believes that consumers who receive extensions of credit made pursuant to a program administered by an HFA do so after a determination of ability to repay using specially tailored criteria. The exemption adopted by the Bureau is limited to creditors or transactions with certain characteristics and qualifications that ensure consumers are offered responsible, affordable credit on reasonably repayable terms. The Bureau thus finds that coverage under the ability-to-repay requirements provides little if any meaningful benefit to consumers in the form of useful protection, given the nature of the credit extended through HFAs. At the same time, the Bureau is concerned that the narrow class of creditors subject to the exemption may either cease or severely curtail mortgage lending if the ability-to-repay requirements are applied to their transactions, resulting in a denial of access to credit. Accordingly, the Bureau is adopting § 1026.43(a)(3)(iv) as proposed, which provides that an extension of credit made pursuant to a program administered by an HFA, as defined under 24 CFR 266.5, is exempt from § 1026.43(c) through (f).

The Bureau is adopting new comment 43(a)(3)(iv)–1 to provide additional clarification which will facilitate compliance. As discussed above, the Bureau understands that most HFA programs are ''mortgage purchase'' programs in which the HFA establishes program requirements (*e.g.,* income limits, purchase price limits, interest rates, points and term limits, underwriting standards, etc.), and agrees to purchase loans made by private creditors that meet these requirements. As a result, the success of these programs in large part depends upon the participation of private creditors. The Bureau intended the exemption to apply to both extensions of credit by HFAs and extensions of credit by private creditors under a mortgage purchase or similar HFA program. The comment clarifies that both extensions of credit made by HFAs directly to consumers as well as extensions of credit made by other creditors pursuant to a program administered by an HFA are exempt from the requirements of § 1026.43(c) through (f). In addition, as discussed above in part II.A, the Bureau understands that HFAs are generally funded through tax-exempt bonds (also known as mortgage revenue bonds), but may receive other types of funding, including funding through Federal programs such as the HOME Program, which is the largest Federal block grant for affordable housing. The Bureau intended the exemption to apply to extensions of credit made pursuant to a program administered by an HFA, regardless of the funding source. The comment clarifies that the creditor is exempt from the requirements of § 1026.43(c) through (f) regardless of whether the program administered by an HFA receives funding from Federal, State, or other sources.

Section 1026.43(a)(3)(iv) is adopted pursuant to the Bureau's authority under section 105(a) and (f) of TILA. Pursuant to section 105(a) of TILA, the Bureau generally may prescribe regulations that provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary or proper to effectuate the purposes of TILA, among other things. For the reasons discussed in more detail above, the Bureau believes that this exemption is necessary and proper to effectuate the purposes of TILA, which include purposes of section 129C, by ensuring that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay. The Bureau believes that mortgage loans originated pursuant to programs administered by HFAs sufficiently account for a consumer's ability to repay, and the exemption ensures that consumers are able to receive assistance under these programs. Furthermore, without the exemption the Bureau believes that consumers in this demographic are at risk of being denied access to the responsible, affordable credit offered under these programs, which is contrary to the purposes of TILA. This exemption is consistent with the findings of TILA section 129C by ensuring that consumers are able to obtain responsible, affordable credit from the creditors discussed above.

The Bureau has considered the factors in TILA section 105(f) and believes that, for the reasons discussed above, an exemption is appropriate under that provision. Pursuant to TILA section 105(f) the Bureau may exempt by regulation from all or part of this title all or any class of transactions for which in the determination of the Bureau coverage does not provide a meaningful benefit to consumers in the form of useful information or protection. In determining which classes of transactions to exempt the Bureau must consider certain statutory factors. For the reasons discussed above, the Bureau exempts an extension of credit made pursuant to a program administered by an HFA because coverage under the ability-to-repay regulations does not provide a meaningful benefit to consumers in the form of useful protection in light of the nature of the credit extended through HFAs. Consistent with its rationale in the proposed rule, the Bureau believes that the exemption is appropriate for all affected consumers to which the exemption would apply, regardless of their other financial arrangements, financial sophistication, or the importance of the loan to them. Similarly, the Bureau believes that the exemption is appropriate for all affected loans covered under the exemption, regardless of the amount of the loan and whether the loan is secured by the principal residence of the consumer. Furthermore, the Bureau believes that, on balance, the exemption will simplify the credit process without undermining the goal of consumer protection, denying important benefits to consumers, or increasing the expense of the credit process. Based on these considerations and the analysis discussed elsewhere in this final rule, the Bureau believes that the exemptions are appropriate. Therefore all credit extended through the Housing Finance Agencies is subject to the exemption.

43(a)(3)(v)

Background

As discussed above, neither TILA nor Regulation Z provides an exemption to the ability-to-repay requirements for creditors, such as nonprofits, that primarily engage in community development lending. However, feedback provided to the Bureau suggested that the ability-to-repay requirements might impose an unsustainable burden on certain creditors offering mortgage loan programs for LMI consumers. The Bureau was concerned that these creditors would not have the resources to implement and comply with the ability-to-repay requirements, and would have ceased or severely limited extending credit to LMI consumers, which would result in the unavailability of responsible, affordable mortgage credit. Accordingly, the Bureau proposed several exemptions intended to ensure that responsible, affordable mortgage credit remained available for LMI consumers.

Credit Extended by CDFIs, CHDOs, and DAPs

The Bureau's proposal. The Bureau proposed to exempt from the ability-to-repay requirements several types of creditors that focus on extending credit

to LMI consumers. Proposed § 1026.43(a)(3)(v)(A) would have exempted an extension of credit made by a creditor designated as a Community Development Financial Institution (CDFI), as defined under 12 CFR 1805.104(h). Proposed § 1026.43(a)(3)(v)(B) would have exempted an extension of credit made by a creditor designated as a Downpayment Assistance Provider of Secondary Financing (DAP) operating in accordance with regulations prescribed by the U.S. Department of Housing and Urban Development applicable to such persons. Proposed § 1026.43(a)(3)(v)(C) would have exempted an extension of credit made by a creditor designated as a Community Housing Development Organization (CHDO), as defined under 24 CFR 92.2, operating in accordance with regulations prescribed by the U.S. Department of Housing and Urban Development applicable to such persons. The Bureau requested feedback regarding whether the requirements imposed in connection with obtaining and maintaining these designations were sufficient to ensure that such creditors provide consumers with responsible and affordable credit, and regarding whether unscrupulous or irresponsible creditors would be able to use these designations to evade the requirements of TILA, extend credit without regard to the consumer's ability to repay, or otherwise harm consumers.

Comments received. The Bureau received many comments addressing the proposed exemptions for creditors designated as a CDFI, CHDO, or DAP. A large number of industry commenters completely opposed the proposed exemptions. These commenters generally argued that the rules should apply equally to all creditors. However, many industry and consumer advocate commenters supported the proposed exemptions. Twenty-five commenters supported the proposed exemption for creditors designated as CDFIs. Also, in response to the Bureau's request for feedback, several commenters provided data related to CDFI underwriting requirements and loan performance. Some commenters specifically discussed and supported the proposed exemption for CHDOs. While several commenters supported the proposed exemption for DAPs, the Bureau received no specific feedback related to these creditors. A few commenters asked the Bureau to consider exemptions for other types of designations or lending programs. For example, a few commenters requested that the Bureau provide a similar exemption for creditors that are chartered members of the NeighborWorks Network, while other commenters requested an exemption for creditors approved as Counseling Intermediaries by HUD.

The Bureau received feedback from several industry commenters requesting that the Bureau provide an exemption for credit unions designated as low-income credit unions (LICUs) by the National Credit Union Administration (NCUA). These commenters explained that the NCUA's LICU designation is similar to the Treasury Department's CDFI designation. However, these commenters stated that most credit unions choose to obtain the LICU designation instead of the CDFI designation. Some commenters suggested that many credit unions are not eligible for CDFI status.

The final rule. The Bureau is adopting the exemptions in a form that is substantially similar to the version proposed. For the reasons discussed below, the Bureau has concluded that a creditor designated as a CDFI or DAP should be exempt from the ability-to-repay requirements, provided these creditors meet certain other applicable requirements. As comments confirmed, creditors seeking these designations must undergo a screening process related to the ability of applicants to provide affordable, responsible credit to obtain the designation and must operate in accordance with the requirements of these programs, including periodic recertification.[140] Comments provided to the Bureau also confirmed that the ability-to-repay requirements generally differ from the unique underwriting criteria which are related to the characteristics of the consumers served by these creditors. The ability-to-repay requirements primarily consist of quantitative underwriting considerations, such as an analysis of the consumer's debt-to-income ratio. In contrast, as discussed in part II.A above, the Bureau understands that creditors with these designations typically engage in a lengthy underwriting process that is specifically tailored to the needs of these consumers by incorporating a variety of compensating factors. Also, although market-wide data is not available for the delinquency rates of credit extended by CHDOs, comments provided to the Bureau related to CDFI loan performance reflect the low default levels associated with these creditors' programs, which strongly suggest that consumers are extended credit on reasonably repayable terms. Finally, commenters confirmed that these creditors serve consumers that have difficulty obtaining responsible and affordable credit, and that the burdens imposed by the ability-to-repay requirements would significantly impair the ability of these creditors to continue serving this market. Taken together, this feedback demonstrates that creditors with these designations provide residential mortgage loans on reasonably repayable terms, that these exemptions are necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers served by these creditors, and that the government approval and oversight associated with these designations ensures that there is little risk that consumers would be subject to abusive lending practices. Thus, the Bureau has determined that it is appropriate to adopt § 1026.43(a)(3)(v)(A) and (B) as proposed.

The Bureau has also concluded that a creditor designated as a CHDO should be exempt from the ability-to-repay requirements. Comments illustrated that, like CDFIs and DAPs, CHDOs generally extend credit on reasonably repayable terms and ensure that LMI consumers have access to responsible, affordable mortgage credit. However, HUD provided comments to the Bureau suggesting that the exemption be narrowed. A person may obtain a CHDO designation for reasons unrelated to residential mortgage lending, such as to acquire tax credits to assist in the development of affordable rental properties. The Bureau believes that it is appropriate to narrow the exemption to only those persons that obtain the CHDO designation for purposes of residential mortgage lending. A person seeking CHDO status to engage in residential mortgage lending must enter into a commitment with the participating jurisdiction developing the project under the HOME Program. The Bureau also believes that providing specific citations to the relevant regulations prescribed by HUD would facilitate compliance. Thus, the Bureau is adopting § 1026.43(a)(3)(v)(C) with language similar to that proposed, but with the additional condition that the creditor designated as a CHDO has entered into a commitment with a participating jurisdiction and is undertaking a project under the HOME Program, pursuant to the provisions of

[140] 24 CFR 200.194(d) provides that HUD certification as an approved nonprofit expires after two years, and nonprofits must reapply for approval prior to the expiration of the two year period. Also, on February 4, 2013 the CDFI Fund required recertification of most CDFIs. *See http://www.cdfifund.gov/news_events/CDFI-2013-06-CDFI_Fund_Releases_Mandatory_Recertification_Guidelines_for_CDFIs.asp.*

24 CFR 92.300(a), and as the terms community housing development organization, commitment, participating jurisdiction, and project are defined under 24 CFR 92.2.

The Bureau acknowledges that creditors with other types of designations also provide valuable homeownership assistance to certain types of consumers or communities. However, the Bureau does not believe that it would be appropriate to provide exemptions for the designations suggested by commenters. For example, while Counseling Intermediaries must be approved by HUD, this approval is not related to the ability of an applicant to provide consumers with responsible and affordable mortgage credit. Furthermore, the Bureau is unaware of evidence suggesting that approval as a Counseling Intermediary is sufficient to ensure that consumers are offered and receive residential mortgage loans on reasonably repayable terms. With respect to the feedback suggesting that the Bureau consider providing an exemption for creditors that are chartered members of the NeighborWorks Network, the Bureau acknowledges that these creditors are also subject to government oversight and seem to provide responsible and affordable mortgage credit. However, the Bureau does not believe that providing an exemption to these creditors would be necessary to ensure access to responsible and affordable credit, as many of these creditors would qualify for one of the exemptions adopted in § 1026.43(a)(3)(v)(A) through (D). Therefore, the Bureau declines to adopt exemptions for the other designations or lending programs suggested by commenters.

In response to feedback provided regarding creditors designated as low-income credit unions, the Bureau conducted additional research and analysis to determine whether an exemption for these creditors would be appropriate. LICUs, like CDFIs, provide credit to low-income consumers. However, NCUA regulations require LICUs to serve only ''predominantly'' low-income consumers, thereby permitting LICUs to extend credit to many consumers with higher incomes.[141] Thus, such an exemption would be too broad and would affect consumers for whom access to credit is not a concern. In addition, the Bureau believes that the small creditor portfolio qualified mortgage loan provisions adopted in § 1026.43(e)(5) will address the concerns raised by commenters and accommodate the needs of small creditors, such as LICUs, while providing consumers with valuable protections. Therefore, the Bureau does not believe that it would be appropriate to provide an exemption for creditors with an LICU designation.

Credit Extended by Certain Nonprofits

The Bureau's proposal. Proposed § 1026.43(a)(3)(v)(D) would have exempted an extension of credit made by a creditor with a tax exemption ruling or determination letter from the Internal Revenue Service under section 501(c)(3) of the Internal Revenue Code of 1986 (26 CFR 1.501(c)(3)–1), provided that certain other conditions were satisfied. Under proposed § 1026.43(a)(3)(iv)(D)(*1*), the exemption would have been available only if the creditor extended credit secured by a dwelling no more than 100 times in the calendar year preceding receipt of the consumer's application. Proposed § 1026.43(a)(3)(v)(D)(*2*) would have further conditioned the exemption on the creditor, in the calendar year preceding receipt of the consumer's application, extending credit secured by a dwelling only to consumers with income that did not exceed the qualifying limit for moderate-income families, as established pursuant to section 8 of the United States Housing Act of 1937 and amended from time to time by the U.S. Department of Housing and Urban Development. Proposed § 1026.43(a)(3)(v)(D)(*3*) would have made the proposed exemption available only if the extension of credit was to a consumer with income that did not exceed this qualifying limit. Finally, proposed § 1026.43(a)(3)(v)(D)(*4*) would have made the proposed exemption contingent upon the creditor determining, in accordance with written procedures, that the consumer had a reasonable ability to repay the extension of credit.

Proposed comment 43(a)(3)(v)(D)–1 would have clarified that an extension of credit is exempt from the requirements of § 1026.43(c) through (f) if the credit is extended by a creditor described in § 1026.43(a)(3)(v)(D), provided the conditions specified in that section are satisfied. The conditions specified in § 1026.43(a)(3)(v)(D)(*1*) and (*2*) are determined according to activity that occurred in the calendar year preceding the calendar year in which the consumer's application was received. Section 1026.43(a)(3)(v)(D)(*2*) provides that, during the preceding calendar year, the creditor must have extended credit only to consumers with income that did not exceed the qualifying limit then in effect for moderate-income families, as specified in regulations prescribed by HUD pursuant to section 8 of the United States Housing Act of 1937. For example, a creditor has satisfied the requirements of § 1026.43(a)(3)(v)(D)(*2*) if the creditor demonstrates that the creditor extended credit only to consumers with income that did not exceed the qualifying limit in effect on the dates the creditor received each consumer's individual application. The condition specified in § 1026.43(a)(3)(v)(D)(*3*), which relates to the current extension of credit, provides that the extension of credit must be to a consumer with income that does not exceed the qualifying limit specified in § 1026.43(a)(3)(v)(D)(*2*) in effect on the date the creditor received the consumer's application. For example, assume that a creditor with a tax exemption ruling under section 501(c)(3) of the Internal Revenue Code of 1986 has satisfied the conditions identified in § 1026.43(a)(3)(v)(D)(*1*) and (*2*). If, on May 21, 2014, the creditor in this example extends credit secured by a dwelling to a consumer whose application reflected income in excess of the qualifying limit identified in § 1026.43(a)(3)(v)(D)(*2*), the creditor has not satisfied the condition in § 1026.43(a)(3)(v)(D)(*3*) and this extension of credit is not exempt from the requirements of § 1026.43(c) through (f).

The Bureau solicited comment regarding whether the proposed exemption was appropriate. The Bureau also specifically requested feedback on whether the proposed 100 transaction limitation was appropriate, on the costs of implementing and complying with the ability-to-repay requirements that would be incurred by creditors that extend credit secured by a dwelling more than 100 times a year, the extent to which this proposed condition would affect access to responsible, affordable credit, and whether the limit of 100 transactions per year should be increased or decreased. The Bureau also requested comment regarding the costs that nonprofit creditors would incur in connection with the ability-to-repay requirements, the extent to which these additional costs would affect the ability of nonprofit creditors to extend credit to LMI consumers, and whether consumers could be harmed by the proposed exemption. The Bureau solicited comment regarding whether the proposed exemption should be extended to creditors designated as nonprofits under section 501(c)(4) of the Internal Revenue Code of 1986. The Bureau also requested financial reports

[141] ''The term *predominantly* is defined as a simple majority.'' 12 CFR 701.34(a)(3).

and mortgage lending activity data supporting the argument that the marginal cost of implementing and complying with the ability-to-repay requirements would cause 501(c)(4) nonprofit creditors to cease, or severely limit, extending credit to LMI consumers.

Comments received. The Bureau received many comments addressing this proposed exemption. Many commenters completely opposed the proposed exemption for community-focused creditors. These commenters generally argued that the rules should apply equally to all creditors. One industry commenter argued that a better approach would be to create special ability-to-repay requirements tailored to the unique underwriting characteristics of LMI consumers. Many other commenters approved of the proposed exemption, including the Bureau's proposed conditions. Several commenters stated that an exemption for certain nonprofits was necessary, but requested various modifications. Most of the commenters that approved of the proposed exemption were concerned that the exemption could be used as a loophole to harm consumers and agreed that conditions were needed to address this potential risk.

Many commenters, including industry, consumer advocate, and nonprofit commenters, explicitly supported the proposed limitation of 100 extensions of credit. These commenters generally explained that the 100-extension limitation was an appropriate limit that would make it difficult for sham nonprofit creditors to harm consumers. However, several commenters asked the Bureau to raise the transaction limitation. The commenters were primarily concerned that the limitation would force nonprofits to limit certain types lending. For example, a few commenters stated that nonprofits that offer both home-purchase mortgage loans and small-dollar mortgage loans, such as for home energy improvement, would limit small-dollar lending to remain under the 100-extension limitation. One nonprofit commenter argued that, for creditors that provide first- and subordinate-lien financing to LMI consumers on the same transaction, the 100-extension limit is effectively a 50-transaction limit. Another nonprofit commenter suggested that the Bureau either apply the 100-extension limit to first-lien mortgage loans, or raise the limit to 500 for total transactions. One consumer advocate commenter suggested raising the limit to 250 transactions per calendar year to address these concerns. A few commenters asked that the Bureau remove the limitation completely. For example, one commenter argued that the Bureau's proposed limit of 100 extensions of credit would harm LMI consumers by raising the cost of credit obtained from larger-scale nonprofit organizations.

One commenter argued that the proposed exemption was too narrow and urged the Bureau to expand the exemption in several ways. First, this commenter argued that the exemption should not be limited to extensions of credit by creditors, but rather should be extended to all transactions in which a nonprofit organization dedicated to providing opportunities for affordable, long-term homeownership is involved, but is not the creditor. This commenter also asked the Bureau to provide no-action letters that would provide a safe harbor for certain mortgage lending programs. In addition, this commenter argued that the proposed references to the low- to moderate-income threshold under section 8 of the National Housing Act was inappropriate because use of the threshold would result in the denial of credit to consumers with income slightly above the threshold. Furthermore, this commenter asserted that it would be arbitrary and unjustified for the Bureau to extend an exemption to State HFAs but not provide an exemption to organizations that rely on underwriting criteria similar to those used by State HFAs, such as the consideration of a consumer's life circumstances. Finally, this commenter disputed the Bureau's justification for the proposed exemptions—that access to credit for LMI consumers would be impaired if certain creditors did not have the resources to implement and comply with the ability-to-repay requirements and ceased or severely limited extending credit—by arguing that LMI consumers are harmed when any creditor, regardless of size, spends money on regulatory compliance that would otherwise have been lent to LMI consumers.

One consumer advocate group opposed providing an exemption for nonprofit creditors and instead suggested several modifications to the ability-to-repay requirements intended to address the Bureau's concerns regarding nonprofits. This commenter argued that, rather than providing an exemption for the proposed categories of nonprofit creditor, the Bureau should provide a rebuttable presumption of compliance for these nonprofit creditors, without requiring the nonprofits to satisfy the requirements of § 1026.43(c) through (f). Also, this commenter argued, these provisions should apply to only bona fide nonprofits, so that consumers would be provided legal recourse against unscrupulous creditors operating sham nonprofits. Further, this commenter suggested that the Bureau should expand the anti-evasion provisions of § 1026.43(h) to include the adoption of nonprofit status for purposes of avoiding the ability-to-repay requirements. This commenter argued that such modifications would provide genuine nonprofits with relief from the regulatory and compliance burdens associated with the ability-to-repay requirements, while enabling consumers to seek recourse against abusive, sham nonprofits.

The Bureau did not receive feedback regarding whether the proposed exemption should be extended to creditors designated as nonprofits under section 501(c)(4) of the Internal Revenue Code of 1986. However, several credit unions and State credit union associations requested that the Bureau expand the nonprofit exemption to all credit unions, as credit unions are designated as nonprofits under sections 501(c)(1) and 501(c)(14) of the Internal Revenue Code of 1986. These commenters generally explained that credit unions, like the nonprofit creditors addressed in the Bureau's proposal, are often small businesses that have difficulty complying with regulatory burdens. Industry commenters also requested an exemption for certain creditors that extend credit to LMI consumers, or for certain programs intended to facilitate access to credit for LMI consumers. For example, some commenters argued that the Bureau should provide an exemption for credit unions operating in certain areas, such as areas defined as ''underserved'' under the Federal Credit Union Act, while others argued that the Bureau should provide an exemption for loans that meet the regulatory requirements of the Community Reinvestment Act or similar programs. These commenters generally argued that such an exemption would facilitate access to credit for LMI consumers by minimizing the regulatory burdens imposed by the ability-to-repay requirements.

A few industry and consumer advocate commenters asked the Bureau to establish a publicly accessible database of all nonprofits that qualified for the exemption. These commenters argued that such a database would facilitate compliance and allow consumers to determine if nonprofit creditors were actually exempt from the requirements. A State attorney general expressed concern about potential abuse and asked the Bureau to consider

vigorous oversight of nonprofits eligible for the exemption.

The final rule. The Bureau is adopting § 1026.43(a)(3)(v)(D) in a form that is substantially similar to the version proposed, except that the Bureau is increasing the annual originations limit from 100 to 200 extensions of credit. For the reasons discussed below, the Bureau has concluded that the exemption should apply provided that, in additional to the annual originations limit: (1) The creditor is designated as a nonprofit organization under section 501(c)(3) of the Internal Revenue Code; (2) the extension of credit is to a consumer with income that does not exceed the limit for low- and moderate-income households as established pursuant regulations prescribed by the U.S. Department of Housing and Urban Development; (3) during the calendar year preceding receipt of the consumer's application the creditor extended credit only to consumers with income that did not exceed the above limit; and (4) the creditor determines, in accordance with written procedures, that the consumer has a reasonable ability to repay the extension of credit. Comments provided to the Bureau generally confirmed that these conditions were reasonable and appropriate measures to ensure that the exemption would not be used as a loophole to avoid the ability-to-repay requirements. Thus, the Bureau has determined that it is appropriate to adopt § 1026.43(a)(3)(v)(D)(*2*), (*3*), and (*4*) generally as proposed, but with technical modifications to paragraphs (a)(3)(v)(D)(*2*) and (*3*), as discussed below.

However, upon further consideration of the comments received, the Bureau has determined that it is appropriate to raise the threshold in proposed § 1026.43(a)(3)(v)(D)(*1*) from 100 to 200 extensions of credit. Most commenters agreed with the rationale advanced in the 2013 ATR Proposed Rule that a limitation is necessary to prevent the exemption from being exploited by unscrupulous creditors seeking to harm consumers. The Bureau strongly believes that this risk outweighs the costs that a limitation may impose on some nonprofit creditors. While many commenters approved of the proposed 100-extension limitation, the Bureau is concerned that this limitation could lead to unintended consequences. The Bureau is particularly concerned that nonprofit creditors providing primary and subordinate financing on the same transaction effectively would be limited to 50 transactions per year. The Bureau did not intend to propose such a strict limitation. The Bureau has concluded that a 200-extension limitation, doubling the 100-extension limit to capture creditors making first- and subordinate-lien loans on the same transaction, would address the concerns raised by commenters while achieving the original intent of the proposed condition. The Bureau does not agree with the suggestions proposed by some commenters that separate limits for first- and subordinate-lien loans should be implemented. The Bureau believes that such a restriction would be needlessly restrictive, and it would be more efficient to allow nonprofit creditors to determine the most efficient allocation of funds between primary and subordinate financing. Furthermore, the Bureau does not agree with the arguments raised by commenters that the threshold should be raised above 200, such as to 500 transactions. As explained in the 2013 ATR Proposed Rule, the Bureau intended to narrowly tailor the exemption to small nonprofits that did not have the resources to bear the burdens associated with the ability-to-repay requirements, and solicited feedback regarding whether a 100 extension of credit limit was indicative of such a resource limitation.[142] While feedback indicated that a 200-extension limitation would more appropriately address the Bureau's intentions, the Bureau received no feedback indicating that nonprofit creditors making more than 200 extensions of credit lacked the resources to implement and comply with the ability-to-repay requirements. The Bureau believes that creditors originating such a number of mortgage loans likely have the resources to bear the implementation and compliance burden associated with the ability-to-repay requirements, unlike smaller nonprofit creditors that make fewer loans. Therefore, as adopted, § 1026.43(a)(3)(v)(D)(*1*) conditions the exemption from the ability-to-repay requirements on the creditor extending credit secured by a dwelling no more than 200 times during the calendar year preceding receipt of the consumer's application.

As discussed above, one commenter argued that the Bureau should limit the exemption to bona fide nonprofit creditors. Adding a bona fide nonprofit condition would provide another avenue for consumers to seek redress against harmful lending practices, which may deter persons from using the exemption as a loophole. However, the Bureau believes that the requirements of § 1026.43(a)(3)(v)(D) are narrowly tailored to protect consumers and limit the risk that an unscrupulous creditor could create a nonprofit for the purpose of extending credit in a harmful, reckless, or abusive manner. Therefore, the Bureau declines to adopt an additional bona fide nonprofit requirement at this time. As with the other exemptions to the ability-to-repay requirements, the Bureau will monitor the mortgage market and may reevaluate this issue if circumstances warrant reconsideration.

As discussed above, one commenter suggested that the Bureau adopt a qualified mortgage definition with a rebuttable presumption of compliance instead of an exemption to the ability-to-repay requirements. The Bureau does not believe it is necessary to adopt a qualified mortgage definition for nonprofit creditors meeting the conditions of § 1026.43(a)(3)(v)(D). The Bureau believes that an exemption is a more effective method of addressing the concerns discussed above. The Bureau believes that a rebuttable presumption would re-introduce the compliance burdens on certain nonprofits that the Bureau seeks to alleviate. Furthermore, the line between a safe harbor and a rebuttable presumption was determined based on pricing thresholds and providing a rebuttable presumption based on other criteria is inconsistent with the approach taken in the 2013 ATR Final Rule. Nor does the Bureau believe that modifying the anti-evasion provisions of § 1026.43(h) is necessary. Either approach would increase regulatory complexity for these creditors, and may frustrate the goals the Bureau seeks to achieve in accommodating nonprofit creditors. The Bureau also has decided that it is inappropriate to provide no-action letters for certain creditors, as suggested by one commenter. For the reasons discussed in this section, the Bureau believes that the exemptions adopted in this final rule are the optimal approach for providing access to responsible, affordable credit while ensuring that consumers are offered and receive mortgage credit on reasonably repayable terms.

The Bureau has also determined that it is appropriate to limit the exemption to creditors designated as nonprofits under section 501(c)(3), but not 501(c)(4), of the Internal Revenue Code of 1986. The Bureau recognizes that these creditors also may be affected by the ability-to-repay requirements. However, the Bureau believes that this distinction is appropriate. As discussed in the 2013 ATR Proposed Rule, this exemption is premised on the belief that the additional costs imposed by the ability-to-repay requirements will force certain nonprofit creditors to cease extending credit, or substantially limit

[142] *See* 78 FR 6644 (Jan. 30, 2013).

credit activities, thereby harming low- to moderate-income consumers.[143] The Bureau solicited comment regarding whether the exemption should be extended to creditors designated as nonprofits under section 501(c)(4) of the Internal Revenue Code of 1986. The Bureau also requested financial reports and mortgage lending activity data supporting the argument that the marginal cost of implementing and complying with the ability-to-repay requirements would cause 501(c)(4) nonprofit creditors to cease, or severely limit, extending credit to low- to moderate-income consumers. The Bureau received no comment in response to this request. Thus, the Bureau concludes that it is appropriate to limit the exemption to creditors designated as nonprofits under section 501(c)(3) of the Internal Revenue Code of 1986, and adopts § 1026.43(a)(3)(v)(D) as proposed.

As noted above, the Bureau received a comment suggesting that the exemption should not be limited to extensions of credit by a creditor but, rather, should be extended to other transactions in which a nonprofit organization that is dedicated to providing opportunities for affordable, long-term homeownership is involved, but is not the creditor. While the Bureau believes that such organizations provide valuable assistance to LMI consumers, the Bureau has determined that it would be inappropriate to extend the exemption in this manner. The exemptions adopted by the Bureau are limited to creditors or transactions where the Bureau believes that consumers are offered and receive residential mortgage loans on reasonably repayable terms. The proposed exemption involves creditors with certain characteristics that ensure consumers are offered responsible, affordable credit on reasonably repayable terms. In these narrow circumstances the Bureau has determined that there is little risk of harm to consumers. However, adopting the approach suggested in this comment effectively would expand the exemption to all creditors, as any creditor could involve such a nonprofit organization in some capacity during the origination process. Such a broad expansion would not be necessary or proper to effectuate the purposes of TILA; to the contrary, it would instead exempt a potentially large number of creditors from the ability-to-repay requirements. The Bureau would not be able to determine if each potential creditor extended credit only on reasonably repayable terms and does not believe it would be appropriate to assume that any involvement by a nonprofit organization is sufficient to ensure that consumers were not harmed by the exemption. Therefore, the Bureau declines to extend the exemption to transactions involving nonprofit organizations that are dedicated to providing opportunities for affordable homeownership.

With respect to the comment disputing the Bureau's justification for the proposed exemptions, the Bureau believes that this criticism results from a misunderstanding of the Bureau's rationale for the proposed exemptions. As explained in the 2013 ATR Proposed Rule, the Bureau may provide an exemption to the ability-to-repay requirements if the statutory conditions for the use of such an exemption are met.[144] Providing an exemption for a particular class of creditors requires a careful balancing of considerations, including the nature of credit extended, safeguards or other factors that may protect consumers from harm, and the extent to which application of the regulatory requirements would affect access to responsible, affordable credit. As discussed in the Bureau's proposal, the Bureau was concerned about creditors that would be forced to cease or severely limit lending to LMI consumers.[145] Based on feedback provided in response to this question, the Bureau has adopted an exemption narrowly tailored to the situations where an exemption is necessary and proper.

The Bureau also disagrees with the arguments advanced that limiting the exemption to creditors extending credit to consumers with income below the qualifying limit for moderate income families as established pursuant to section 8 of the United States Housing Act of 1937 is arbitrary. The Bureau acknowledges that there may be cases where a consumer with income slightly above the LMI threshold is unable to secure credit. However, most commenters agreed that these conditions helped ensure that the proposed exemption would not become a regulatory loophole by which consumers could be harmed. Thus, the Bureau believes that it is necessary to draw a line, and the section 8 income limitations are clear and well-known. Such an approach will facilitate compliance while ensuring that the exemption is narrowly tailored to address the consumers for whom access to credit is a concern. Therefore, the Bureau has concluded that it is appropriate to refer to these qualifying income limits. Furthermore, the Bureau intends to monitor these qualifying income limits in the future to ensure that the exemption remains narrowly tailored. The Bureau has determined that it is necessary to make a technical change to the proposed language. Although HUD's qualifying income limits are colloquially referred to as ''section 8 limits,'' the thresholds were established by section 102 of the Housing and Community Development Act of 1974, which amended the National Housing Act of 1937. The Bureau believes that it is appropriate to identify the thresholds by the exact statutory and regulatory reference. Accordingly, the Bureau is adopting § 1026.43(a)(3)(v)(D)(*2*) and (*3*) generally as proposed, but with a technical modification that refers to the low- and moderate-income household limit as established pursuant to section 102 of the Housing and Community Development Act of 1974.

As discussed above, several commenters asked the Bureau to remain engaged with the nonprofit community to ensure that the exemption is not used as a loophole to harm consumers. For example, some commenters asked the Bureau to establish a database of creditors that qualify for the § 1026.43(a)(3)(v)(D) exemption. The Bureau intends to keep abreast of developments in the mortgage market, including lending programs offered by nonprofit creditors pursuant to this exemption. However, the Bureau does not believe that it is necessary to develop a formal oversight mechanism, such as a database of creditors eligible for this exemption, at this time. Instead, the Bureau will continue to collect information related to the effectiveness of the ability-to-repay requirements, including the § 1026.43(a)(3)(v)(D) exemption, and will pursue additional rulemakings or data collections if the Bureau determines in the future that such action is necessary.

The Bureau has also carefully considered the comments requesting a full or limited exemption from the ability-to-repay requirements for certain creditors or for certain programs intended to facilitate access to credit for LMI consumers. For example, as discussed above, several industry commenters argued that the Bureau should provide an exemption for all credit unions, which are designated as nonprofit organizations under sections 501(c)(1) and 501(c)(14) of the Internal Revenue Code of 1986. Other industry commenters argued that the Bureau should provide an exemption for credit unions operating in certain areas, such

[143] *See* 78 FR 6645 (Jan. 30, 2013).

[144] *See* 78 FR 6635–36 (Jan. 30, 2013).

[145] *Id.* at 6643.

as areas defined as ''underserved'' under the Federal Credit Union Act. The Bureau agrees with the arguments advanced by commenters that credit unions were not the source of the financial crisis, have historically employed responsible underwriting requirements, and are often an important source of credit for LMI consumers. However, the Bureau does not believe that any of the requested exemptions for credit unions are necessary. The Bureau understands that many credit unions will qualify for the additional qualified mortgage definitions discussed below in the section-by-section analyses of § 1026.43(e)(5) and (e)(6). Also, given the thoroughness of the traditional underwriting methods employed by credit unions, the Bureau does not believe that larger credit unions will have difficulty complying with the general ability-to-repay requirements or qualified mortgage provisions. Further, absent evidence suggesting that the ability-to-repay requirements would force these credit unions to cease or severely curtail extending credit to LMI consumers, the Bureau does not believe that an exemption would be appropriate. For similar reasons, the Bureau declines to expand the exemption to loans that meet the regulatory requirements of the Community Reinvestment Act or similar programs. The Bureau is not persuaded that such an expansive exemption is necessary to ensure that LMI consumers have access to responsible, affordable credit.

To summarize, the Bureau has determined that an exemption to the ability-to-repay requirements is appropriate for certain nonprofit creditors. The Bureau has modified the proposed exemption in a manner that addressed the concerns raised by various commenters. As adopted, § 1026.43(a)(3)(v)(D) exempts an extension of credit made by a creditor with a tax exemption ruling or determination letter from the Internal Revenue Service under section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3); 26 CFR 1.501(c)(3)–1), provided that all of the conditions in § 1026.43(a)(3)(v)(D)(*1*) through (*4*) are satisfied. Section 1026.43(a)(3)(v)(D)(*1*) conditions the exemption on the requirement that, during the calendar year preceding receipt of the consumer's application, the creditor extended credit secured by a dwelling no more than 200 times. Section 1026.43(a)(3)(v)(D)(*2*) conditions the exemption on the requirement that, during the calendar year preceding receipt of the consumer's application, the creditor extended credit secured by a dwelling only to consumers with income that did not exceed the low- and moderate-income household limit as established pursuant to section 102 of the Housing and Community Development Act of 1974 (42 U.S.C. 5302(a)(20)) and amended from time to time by the U.S. Department of Housing and Urban Development, pursuant to 24 CFR 570.3. Section 1026.43(a)(3)(v)(D)(*3*) conditions the exemption on the requirement that the extension of credit is to a consumer with income that does not exceed the above limit. Section 1026.43(a)(3)(v)(D)(*4*) conditions the exemption on the requirement that the creditor determines, in accordance with written procedures, that the consumer has a reasonable ability to repay the extension of credit. The Bureau is also adopting comment 43(a)(3)(v)(D)–1 generally as proposed, but with technical modifications that reflect the appropriate references to HUD's low- and moderate-income household limit, as described above.

Legal Authority

Section 1026.43(a)(3)(v) is adopted pursuant to the Bureau's authority under section 105(a) and (f) of TILA. Pursuant to section 105(a) of TILA, the Bureau generally may prescribe regulations that provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary and proper to effectuate the purposes of TILA, among other things. For the reasons discussed in more detail above, the Bureau has concluded that this exemption is necessary and proper to effectuate the purposes of TILA, which include the purposes of TILA section 129C. By ensuring the viability of the low- to moderate-income mortgage market, this exemption would ensure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay. The Bureau also believes that mortgage loans originated by these creditors generally account for a consumer's ability to repay. Without the exemption the Bureau believes that low- to moderate-income consumers are at risk of being denied access to the responsible and affordable credit offered by these creditors, which is contrary to the purposes of TILA. This exemption is consistent with the finding of TILA section 129C by ensuring that consumers are able to obtain responsible, affordable credit from the nonprofit creditors discussed above which inform the Bureau's understanding of its purposes.

The Bureau has considered the factors in TILA section 105(f) and has concluded that, for the reasons discussed above, an exemption is appropriate under that provision. Pursuant to TILA section 105(f) the Bureau may exempt by regulation from all or part of this title all or any class of transactions for which in the determination of the Bureau coverage does not provide a meaningful benefit to consumers in the form of useful information or protection. In determining which classes of transactions to exempt, the Bureau must consider certain statutory factors. For the reasons discussed above, the Bureau exempts an extension of credit made by the creditors and under conditions provided in § 1026.43(a)(3)(v) because coverage under the ability-to-repay requirements does not provide a meaningful benefit to consumers in the form of useful protection in light of the protection the Bureau believes that the credit extended by these creditors already provides to consumers. Consistent with its rationale in the 2013 ATR Proposed Rule, the Bureau believes that the exemptions are appropriate for all affected consumers to which the exemption applies, regardless of their other financial arrangements and financial sophistication and the importance of the loan to them. Similarly, the Bureau believes that the exemptions are appropriate for all affected loans covered under the exemption, regardless of the amount of the loan and whether the loan is secured by the principal residence of the consumer. Furthermore, the Bureau believes that, on balance, the exemptions will simplify the credit process without undermining the goal of consumer protection, denying important benefits to consumers, or increasing the expense of the credit process. The Bureau recognizes that its exemption and exception authorities apply to a class of transactions, and has decided to apply these authorities to the loans covered under the final rule of the entities subject to the adopted exemptions.

43(a)(3)(vi)

The Bureau's Proposal

As discussed above, neither TILA nor Regulation Z provides an exemption to the ability-to-repay requirements for Federal programs designed to stabilize homeownership or mitigate the risks of foreclosure. However, the Bureau was concerned that the ability-to-repay requirements would inhibit the effectiveness of these Federal programs. As a result, the Bureau proposed

§ 1026.43(a)(3)(vi), which would have provided that an extension of credit made pursuant to a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5211; 5219) (EESA) is exempt from § 1026.43(c) through (f).

Proposed comment 43(a)(3)(vi)–1 would have explained that the requirements of § 1026.43(c) through (f) did not apply to a mortgage loan modification made in connection with a program authorized by sections 101 and 109 of EESA. If a creditor is underwriting an extension of credit that is a refinancing, as defined by § 1026.20(a), that will be made pursuant to a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008, the creditor also need not comply with § 1026.43(c) through (f). Thus, a creditor need not determine whether the mortgage loan modification is considered a refinancing under § 1026.20(a) for purposes of determining applicability of § 1026.43; if the transaction is made in connection with these programs, the requirements of § 1026.43(c) through (f) do not apply.

The Bureau solicited general feedback regarding whether this proposed exemption was appropriate. In particular, the Bureau sought comment regarding whether applicability of the ability-to-repay requirements would constrict the availability of credit offered under these programs and whether consumers have suffered financial loss or other harm by creditors participating in these programs. The Bureau also requested information on the extent to which the requirements of these Federal programs account for a consumer's ability to repay. The Bureau also sought comment regarding whether, if the Bureau determined that a full exemption is not warranted, what modifications to the general ability-to-repay standards would be warranted and whether qualified mortgage status should be granted instead, and, if so, under what conditions.

Comments Received

The Bureau received several comments addressing this proposed exemption. One consumer advocate commenter opposed the exemption and stated that these programs lack meaningful underwriting guidance. Many industry and consumer advocate commenters supported the exemption. These commenters generally argued that the ability-to-repay requirements would make these programs unworkable, which would frustrate the public policy purposes of EESA and harm consumers in need of assistance. A few industry commenters requested that the Bureau provide an exemption for homeownership stabilization and foreclosure prevention programs, other than those authorized by sections 101 and 109 of EESA, such as a creditor's proprietary program intended to provide assistance to consumers who have experienced a loss of employment or other financial difficulty.

The Final Rule

The Bureau is adopting § 1026.43(a)(3)(vi) and comment 43(a)(3)(vi)–1 as proposed. For the reasons discussed below, the Bureau has determined that an exemption from the ability-to-repay requirements is necessary and appropriate for extensions of credit made pursuant to a program authorized by sections 101 and 109 of EESA. Commenters agreed with the Bureau that the ability-to-repay requirements would interfere with, or are inapplicable to, these programs, which are intended to address the unique underwriting requirements of certain consumers at risk of default or foreclosure. By significantly impairing the effectiveness of these programs, the Bureau believes that there is a considerable risk that the ability-to-repay requirements would actually prevent at-risk consumers from receiving mortgage credit provided in an affordable and responsible manner.

With respect to the feedback provided opposing this exemption, the Bureau believes that, based on the existence of Federal oversight and the EESA requirements, the risk of consumer harm is low. Additionally, as discussed in part II.A above, the Bureau understands that these EESA programs have highly detailed requirements, created and maintained by the Treasury Department, to determine whether EESA assistance will benefit distressed consumers.[146] In addition to satisfying these Treasury Department requirements, consumers receiving assistance under an EESA program must meet EESA eligibility requirements and creditor program requirements.[147] Thus, the Bureau believes that credit available under these programs is extended on reasonably repayable terms and conditions.

Several industry commenters asked the Bureau to consider an exemption for proprietary foreclosure mitigation and homeownership stabilization programs. While the Bureau believes that these programs likely benefit many consumers, the Bureau has determined that an exemption from the ability-to-repay requirements is inappropriate. Proprietary programs are not under the jurisdiction of the U.S. Department of the Treasury, as EESA programs are. This lack of accountability increases the risk that an unscrupulous creditor could harm consumers. Furthermore, EESA programs will expire by 2017 and are intended to provide assistance to a narrow set of distressed consumers. In contrast, the exemption suggested by commenters is potentially indefinite and indeterminate. Also, the Bureau believes that creditors seeking to provide assistance to consumers in distress without incurring the obligations associated with the ability-to-repay requirements may do so by providing a consumer with a workout or similar modification that does not constitute a refinancing under § 1026.20(a). Thus, the Bureau declines to provide an exemption for these proprietary programs.

No commenters addressed whether credit extended pursuant to an EESA program should be granted a presumption of compliance as qualified mortgages, and, if so, under what conditions. However, the Bureau does not believe that extending qualified mortgage status to these loans would be as effective in addressing the concerns raised above as an exemption. Even if credit extended under EESA programs were granted a presumption of compliance as qualified mortgages, creditors extending credit pursuant to these programs could be impacted by significant implementation and compliance burdens. Furthermore, as discussed above, many loans extended under these programs would not appear to satisfy the qualified mortgage standards under § 1026.43(e)(2). For example, consumers receiving assistance under EESA programs may have DTI ratios in excess of the § 1026.43(e)(2)(vi) threshold.[148] Thus, a creditor extending such a mortgage loan—assuming the loan does not qualify for another qualified mortgage definitions—would be required to comply with the ability-to-repay requirements of § 1026.43(c) and, in response to the potential liability for

[146] *See* United States Department of the Treasury, ''Home Affordable Modification Program, Base Net Present Value (NPV) Model v5.02, Model Documentation'' (April 1, 2012).

[147] *See http://www.makinghomeaffordable.gov/programs/Pages/default.aspx*. For example, the EESA PRA program contains several eligibility requirements in addition to program requirements. *See http://www.makinghomeaffordable.gov/programs/lower-payments/Pages/pra.aspx*.

[148] Consumers receiving assistance under EESA programs may have back-end DTI ratios in excess of 50 percent. *See* United States Department of the Treasury, *Making Home Affordable Program Performance Report* (March 2013), page 9, *available at: http://www.treasury.gov/initiatives/financial-stability/reports/Documents/March%202013%20MHA%20Report%20Final.pdf*.

noncompliance, would cease or severely curtail lending under the voluntary EESA programs.

Accordingly, the Bureau believes that the proposed exemption for credit made pursuant to an EESA program is appropriate under the circumstances. The Bureau believes that consumers who receive extensions of credit made pursuant to an EESA program do so after a determination of ability to repay using criteria unique to the distressed consumers seeking assistance under the program. The exemption adopted by the Bureau is limited to creditors or transactions with certain characteristics and qualifications that ensure consumers are offered responsible, affordable credit on reasonably repayable terms. The Bureau thus finds that coverage under the ability-to-repay requirements provides little if any meaningful benefit to consumers in the form of useful protection, given the nature of the credit offered under EESA programs. At the same time, the Bureau is concerned that the narrow class of creditors subject to the exemption may either cease or severely curtail mortgage lending if the ability-to-repay requirements are applied to their transactions, resulting in a denial of access to credit. Accordingly, the Bureau is adopting § 1026.43(a)(3)(vi) as proposed.

Section 1026.43(a)(3)(vi) is adopted pursuant to the Bureau's authority under section 105(a) and (f) of TILA. Pursuant to section 105(a) of TILA, the Bureau generally may prescribe regulations that provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary and proper to effectuate the purposes of TILA, among other things. As discussed in more detail above, the Bureau has concluded that this exemption is necessary and proper to effectuate the purposes of TILA, which include the purposes of TILA section 129C. This exemption would ensure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay. In the Bureau's judgment extensions of credit made pursuant to a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008 sufficiently account for a consumer's ability to repay, and the exemption ensures that consumers are able to receive assistance under these programs. Furthermore, without the exemption the Bureau believes that consumers at risk of default or foreclosure would be denied access to the responsible, affordable credit offered under these programs, which is contrary to the purposes of TILA. This exemption is consistent with the finding of TILA section 129C by ensuring that consumers are able to obtain responsible, affordable credit from the nonprofit creditors discussed above which inform the Bureau's understanding of its purposes.

The Bureau has considered the factors in TILA section 105(f) and has concluded that, for the reasons discussed above, an exemption is appropriate under that provision. Pursuant to TILA section 105(f) the Bureau may exempt by regulation from all or part of this title all or any class of transactions for which in the determination of the Bureau coverage does not provide a meaningful benefit to consumers in the form of useful information or protection. In determining which classes of transactions to exempt, the Bureau must consider certain statutory factors. The Bureau exempts an extension of credit pursuant to a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008 because coverage under the ability-to-repay requirements does not provide a meaningful benefit to consumers in the form of useful protection in light of the protection the Bureau believes that the credit extended through these programs already provides to consumers. Consistent with its rationale in the 2013 ATR Proposed Rule, the Bureau believes that the exemptions are appropriate for all affected consumers to which the exemption applies, regardless of their other financial arrangements and financial sophistication and the importance of the loan to them. Similarly, the Bureau believes that the exemptions are appropriate for all affected loans covered under the exemption, regardless of the amount of the loan and whether the loan is secured by the principal residence of the consumer. Furthermore, the Bureau believes that, on balance, the exemptions will simplify the credit process without undermining the goal of consumer protection, denying important benefits to consumers, or increasing the expense of the credit process. The Bureau recognizes that its exemption and exception authorities apply to a class of transactions, and has decided to apply these authorities to the loans covered under the final rule of the entities subject to the adopted exemptions.

43(a)(3)(vii)

The Bureau's Proposal

As discussed above, neither TILA nor Regulation Z provide an exemption to the ability-to-repay requirements for refinancing programs offered by the Department of Housing and Urban Development (HUD), the Department of Veterans Affairs (VA), or the U.S. Department of Agriculture (USDA). However, comments provided to the Bureau during the development of the 2013 ATR Final Rule suggested that the ability-to-repay requirements would restrict access to credit for consumers seeking to obtain a refinancing under certain Federal agency refinancing programs, that the ability-to-repay requirements adopted by the Bureau should account for the requirements of Federal agency refinancing programs, and that Federal agency refinancing programs should be exempt from several of the ability-to-repay requirements. TILA section 129C(b)(3)(B)(ii), as amended by section 1411 of the Dodd-Frank Act, requires these Federal agencies to prescribe rules related to the definition of qualified mortgage. These Federal agencies have not yet prescribed rules related to the definition of qualified mortgage. Section 1411 of the Dodd-Frank Act addresses refinancing of existing mortgage loans under the ability-to-repay requirements. As amended by the Dodd-Frank Act, TILA section 129C(a)(5) provides that Federal agencies may create an exemption from the income and verification requirements for certain streamlined refinancings of loans made, guaranteed, or insured by various Federal agencies. 15 U.S.C. 1639(a)(5). These Federal agencies also have not yet prescribed rules related to the ability-to-repay requirements for refinancing programs. Section 1026.43(e)(4), as adopted in the 2013 ATR Final Rule, provides temporary qualified mortgage status for mortgage loans eligible to be insured, guaranteed, or made pursuant to a program administered by one of these Federal agencies, until the effective date of the agencies' qualified mortgage rules prescribed pursuant to TILA section 129C(b)(3)(B)(ii). However, the Bureau was concerned that the ability-to-repay requirements would impede access to credit available under these programs. Based on these concerns and to gather more information about the potential effect of the ability-to-repay requirements on Federal agency refinancing programs, the Bureau proposed an exemption for certain refinancings under specified Federal programs and solicited feedback on several issues.

Specifically, proposed § 1026.43(a)(3)(vii) would have provided that an extension of credit that is a refinancing, as defined under

§ 1026.20(a) but without regard for whether the creditor is the creditor, holder, or servicer of the original obligation, that is eligible to be insured, guaranteed, or made pursuant to a program administered by the FHA, VA, or USDA, is exempt from § 1026.43(c) through (f), provided that the agency administering the program under which the extension of credit is eligible to be insured, guaranteed, or made has not prescribed rules pursuant to section 129C(a)(5) or 129C(b)(3)(B)(ii) of TILA. The Bureau solicited comment regarding whether this exemption is appropriate, whether there are any additional conditions that should be required, whether the ability-to-repay requirements would negatively affect the availability of credit offered under Federal agency programs, and whether consumers could be harmed by exempting these extensions of credit from the ability-to-repay requirements.

Comments Received

In response to the proposed rule, most commenters supported the proposed exemption. Industry commenters stated that the Federal agency refinancing programs have successfully provided significant benefits to many individual consumers and have helped stabilize the housing and real estate markets. Industry commenters and an association of State bankers noted that Federal agency refinancing programs are subject to comprehensive requirements and limitations that account for a consumer's ability to repay (*e.g.,* demonstrated payment history), and participating creditors must document and certify program compliance. These commenters also noted that these refinancing programs are in the interest of consumers because they specifically require a demonstrated consumer benefit such as a lower interest rate, lower payment amount, shorter loan term, or more stable mortgage product. Industry commenters and an association of State bankers argued that subjecting these Federal agency refinancing programs to the ability-to-repay requirements would conflict with the objectives of the programs, limit participation and access to these programs, and raise the cost for consumers. Without an exemption from the ability-to-repay requirements, they feared that most Federal agency refinancing programs would not be used, causing communities and homeowners to suffer. Industry commenters noted that the exemption from the ability-to-repay requirements for Federal agency refinancing programs would encourage broad participation in such programs, which are a critical component of the housing market recovery, and in light of the improving, but continued fragile state, of the housing market and broader economy, help support market stability. Industry commenters argued that the exemption would provide more certainty for creditors, which would lead to more of these types of loans being originated.

Several commenters asked the Bureau to clarify which Federal agency refinancing programs would qualify, as programs change, may be replaced, and new programs may develop in the future. In addition, an industry commenter suggested clarifying that events occurring after closing of a loan would not remove the exemption from the ability-to-repay requirements, in order to provide greater certainty for creditors. An industry trade group commenter also argued that the Bureau should exempt not only loans that are eligible for a Federal agency refinancing program, but also loans that are or would be accepted into such program except for a good faith mistake, because otherwise creditors will underwrite to the ability-to-repay requirements in all cases and the benefits of exemption will be severely diminished, if not lost completely.

No commenters addressed whether Federal agency refinancings should or should not be exempt from the ability-to-repay requirements given that FHA, VA, and USDA loans, including refinances, are afforded qualified mortgage status under the Bureau's 2013 ATR Final Rule. Specifically, no commenters addressed the premise that the ability-to-repay requirements could impose significant implementation and compliance burdens on the designated creditors and programs even if credit extended by the designated creditors or under the designated programs were granted a presumption of compliance as qualified mortgages.

Some consumer advocate commenters were strongly opposed to the exemption, asserting that assessment of a consumer's ability to repay is of paramount importance under the statutory scheme. These commenters contended that consumers could be harmed by exempting these extensions of credit from the ability-to-repay requirements. The primary arguments were that serial refinancings (and the resulting equity-stripping) were a root cause of the financial crisis, and that the proposed exemption would leave consumers with no recourse. These commenters argued that such serial refinancings were often not voluntarily chosen by the consumer, but, instead, were temporary measures that delayed foreclosure or were driven by a loan originator seeking more business. Consumer group commenters argued that Federal agency refinance guidelines do not contain adequate assurances of ability to repay, and asserted that FHA streamlined refinances are available with no requirement to underwrite for affordability and VA streamlined refinances are also available without any proof of income or appraisal. One consumer group commenter stressed that the ability-to-repay requirements were intended to protect consumers from equity-stripping or other forms of predatory refinancing practices that harmed so many consumers, and that refinancing an unaffordable loan with other loans that are not responsible or affordable does not help consumers. This commenter argued that consumers do not benefit when they receive loans they cannot afford, nor do they benefit when a refinance that costs money and strips the consumer of equity simply delays the inevitable reality that the consumer cannot afford his or her home. This commenter also stated that the proposed exemption would immunize creditors from TILA liability with respect to refinancings offered to some of the most vulnerable consumers, enabling unscrupulous creditors to engage in serial refinancings that harm consumers. This commenter also disputed the contention raised by others that the ability-to-repay requirements are costly and burdensome by asserting that the Bureau's provisions comprise basic underwriting requirements that all creditors should consider before extending refinancing credit. This commenter argued that it is not difficult to determine a consumer's ability to repay a loan, and that the Bureau's ability-to-repay requirements are straightforward, streamlined, and should become the industry standard for all loans, whether purchase money or refinancings. A State attorney general also argued that the proposed exemption would affect a large segment of the mortgage market, thereby potentially placing a large number of consumers at risk while undermining the Bureau's goal of providing uniform standards for the entire mortgage loan industry.

Consumer group commenters and a State attorney general also observed that these Federal agencies have not yet prescribed rules related to the ability-to-repay requirements for refinances, pursuant to TILA section 129C(a)(5), or the definition of qualified mortgage, pursuant to TILA section 129C(b)(3)(B)(ii), but that they have nearly a year before the 2013 Final Rule goes into effect, which is ample time for

them to issue their own rules under the Dodd-Frank Act. Accordingly, the State attorney general argued that consumers' access to credit will not be seriously prejudiced by a temporary application of the ability-to-repay requirements because these Federal agency rules are likely forthcoming. Consumer group commenters and the State attorney general argued that Federal agencies should be bound by the ability-to-repay requirements between now and the time they issue their own new rules. These commenters argued that exempting Federal agency refinancing programs from the ability-to-repay requirements before they have promulgated their own rules removes an incentive for the agencies to promulgate their own rules in a timely manner while opening up the possibility that creditors acting pursuant to Federal agency refinancing programs could originate loans that are not responsible or affordable in the interim, thereby endangering the most vulnerable consumers who receive these loans.

The Final Rule

The Bureau is withdrawing the proposed exemption for the reasons below. Upon further review and consideration of the comments received, the Bureau has determined that the proposed exemption would be inappropriate. As discussed in the Bureau's proposal, the Bureau was concerned that the ability-to-repay requirements and qualified mortgage provisions would restrict access to credit for certain consumers seeking to obtain a refinancing. After performing additional analysis prompted by the comments received, the Bureau believes that the qualified mortgage provision under § 1026.43(e)(4), which generally provides qualified mortgage status to loans that are eligible for purchase, insurance, or guarantee by the specified Federal agencies, including refinancings, strikes the appropriate balance between preserving consumers' rights to seek redress for violations of TILA and ensuring access to responsible, affordable credit during the current transition period.

The Bureau agrees with the arguments raised by commenters that Federal agency refinancing programs have helped stabilize the housing and real estate markets. The Bureau also acknowledges that these programs are subject to comprehensive underwriting requirements that account for a consumer's ability to repay, which helps ensure that consumers receive access to credit. Although many commenters approved of the proposed exemption for the above reasons, these commenters did not address the costs and benefits of the proposed exemption in light of the qualified mortgage status granted to loans that are eligible for purchase, insurance, or guarantee by the specified Federal agencies under the Bureau's 2013 ATR Final Rule. Specifically, even absent an exemption from the ability-to-repay requirements, FHA, VA, and USDA loans, including refinancings, are given qualified mortgage status under the Bureau's 2013 ATR Final Rule, which provides for a temporary category of qualified mortgages for loans that satisfy the underwriting requirements of, and are therefore eligible to be purchased, guaranteed, or insured by HUD, VA, USDA, or RHS. This temporary provision will expire when qualified mortgage regulations issued by the various Federal agencies become effective, and in any event after seven years.

Section 1026.43(e)(4) addresses any inconsistencies that may occur between the general ability-to-repay and qualified mortgage provisions of the 2013 ATR Final Rule and Federal agency requirements, which should maintain the status quo in the Federal agency refinancing market and ensure that consumers are able to obtain responsible, affordable refinancing credit under these programs. Under the temporary qualified mortgage provisions in § 1026.43(e)(4), for instance, creditors need only comply with the documentation and underwriting requirements established by the respective Federal agencies, and need not apply the 43 percent debt-to-income ratio or follow the documentation and underwriting procedures applicable to the general category of qualified mortgages under § 1026.43(e)(3) and appendix Q. Since the Federal agency eligibility generally satisfies the requirements of § 1026.43(e)(4), the Bureau does not believe that the qualified mortgage provisions are inconsistent with the requirements of Federal agency refinancing programs.

Under the qualified mortgage provision in § 1026.43(e)(4), a loan that is eligible to be purchased, guaranteed, or insured by the specified Federal agencies would still need to meet certain minimum requirements imposed by the Dodd-Frank Act. To receive qualified mortgage status, in addition to Federal agency-eligibility, § 1026.43(e)(4)(i)(A) provides that a mortgage loan may not include the higher-risk loan terms identified in § 1026.43(e)(2)(i) (*e.g.,* negative amortization and interest-only payments), may not have a loan term that exceeds 30 years, and may not impose points and fees in excess of the thresholds in § 1026.43(e)(3). However, while some Federal agency refinancings may not be eligible for qualified mortgage status, the Bureau does not believe that many Federal agency refinancings would fail to meet these minimum requirements. Although some Federal agency refinancings may contain the risky features identified in § 1026.43(e)(2)(i) and provide for loan terms in excess of 30 years, the Bureau does not believe that many consumers receive such loans. Further, while market-wide data regarding points and fees on Federal agency refinancings is not available, the Bureau does not believe that many Federal agency refinancings would provide for points and fees in excess of the § 1026.43(e)(3) thresholds. Refinancings are usually less complicated than purchase transactions. Therefore, refinancings generally require fewer costs, which makes it unlikely that a Federal agency refinancing would exceed the points and fees thresholds and loans under these programs. In addition, the Bureau did not receive comment suggesting that points and fees on Federal agency refinancings exceed the § 1026.43(e)(3) thresholds. In any event, to the extent that eligibility for qualified mortgage status based upon these minimum requirements becomes an issue, the Bureau notes that the various Federal agencies can address any eligibility concerns when they prescribe their own detailed regulations concerning qualified mortgages and refinancings. Importantly, as discussed in the 2013 ATR Final Rule, the Bureau believes that Congress intended for loans with these risky features, long loan terms, or high points and fees to be excluded from the scope of the qualified mortgage definition. As the Bureau believes that few Federal agency refinancings would fail to meet these minimum statutory requirements, the Bureau does not believe that a modification is necessary to ensure access to responsible, affordable credit.

The Bureau believes that the temporary qualified mortgage provisions will help ensure that Federal agency refinancing programs will continue to be used and provide more certainty for creditors, which will lead to more of these types of loans being originated, and encourage broad participation in such programs, which will help support market stability. Thus, the Bureau disagrees with the concerns raised by some commenters that the withdrawal of the exemption would conflict with the objectives of the programs, limit participation and access to these programs, impair the effectiveness of

such programs, or raise the cost for consumers. The Bureau believes that it has provided a sufficient transition mechanism until the various Federal agencies can prescribe their own regulations concerning qualified mortgages and refinancings.

In addition, the Bureau believes that the temporary qualified mortgage definition more appropriately balances risks to consumers than a full exemption until such time as the Federal agencies can address the concerns raised by commenters in their own detailed rulemakings. The Bureau agrees that the ability-to-repay requirements were intended, in part, to prevent harmful practices such as equity stripping and other forms of predatory refinancings. The Bureau's temporary qualified mortgage provision provides additional protection to consumers and preserves potential claims in the event of abuse. For higher-priced qualified mortgages, consumers will still have the ability to assert a claim under TILA section 130(a) and (k) and prove that, despite the presumption of compliance attached to the qualified mortgage, the creditor nonetheless failed to comply with the ability-to-repay requirements. A consumer who prevails on such a claim may be able to recover special statutory damages equal to the sum of all finance charges and fees paid within the first three years after consummation, among other damages and costs, and may be able to assert the creditor's failure to comply to obtain recoupment or setoff in a foreclosure action even after the statute of limitations for affirmative claims has passed. The Bureau received no persuasive evidence that the qualified mortgage provisions of § 1026.43(e)(4) fail to strike the appropriate balance between consumer protection and the needs of the mortgage lending market during the current transition period.

Based on these considerations, the Bureau has determined that the withdrawal of this proposed exemption would ensure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay. Based on the qualified mortgage status, the Bureau does not believe that the ability-to-repay requirements would significantly interfere with requirements of these Federal agency refinancing programs, make it more difficult for many consumers to qualify for these programs, or increase the cost of credit for those who do. The Bureau believes that the temporary qualified mortgage definition for loans that are eligible for purchase, insurance, or guarantee by the specified Federal agencies adequately addresses concerns about overlapping underwriting requirements while also preserving consumers' rights to seek redress if an abuse occurs. Accordingly, the Bureau concludes that this temporary exemption is not necessary to preserve access to affordable and responsible credit, and, therefore, is withdrawing the proposed exemption.

As discussed above, several industry commenters requested various modifications to the proposed language. For example, some commenters asked the Bureau to clarify which Federal agency refinancing programs would qualify for the exemption from the ability-to-repay requirements, as programs change, may be replaced, and new programs may develop in the future. An industry commenter suggested clarifying that events occurring after closing of a loan would not remove the exemption from the ability-to-repay requirements, in order to provide greater certainty for creditors. In addition, an industry trade group commenter argued that the Bureau should exempt not only loans that are eligible for a Federal agency refinance program, but also loans that are or would be accepted into such program except for a good faith mistake. As the Bureau has decided to withdraw proposed § 1026.43(a)(3)(vii), the issues addressed in these and similar comments are moot. As discussed above, mortgage loans that are eligible for purchase, insurance, or guarantee by the specified Federal agencies receive the temporary qualified mortgage status under § 1026.43(e)(4), provided the requirements of that paragraph are met.

43(a)(3)(viii)

The Bureau's Proposal

As discussed above, neither TILA nor Regulation Z provides an exemption to the ability-to-repay requirements for particular lending programs. However, comments provided to the Bureau during the development of the 2013 ATR Final Rule suggested that the ability-to-repay requirements would restrict access to credit for consumers seeking to obtain a refinancing under certain GSE programs for mortgage loans with high loan-to-value ratios or for consumers harmed by the financial crisis. These programs include HARP, which was defined as an ''eligible targeted refinancing program'' in regulations promulgated by FHFA, to replace high loan-to-value mortgage loans with affordable refinancings.[149] To gather more information about the potential effect of the ability-to-repay requirements on programs such as HARP and explore a potential exemption, the Bureau proposed § 1026.43(a)(3)(viii), which would have provided that an extension of credit that is a refinancing, as defined under § 1026.20(a) but without regard for whether the creditor is the creditor, holder, or servicer of the original obligation, that is eligible for purchase or guarantee by Fannie Mae or Freddie Mac is exempt from § 1026.43(c) through (f). This proposed exemption would have applied provided that: (1) The refinancing is made pursuant to an eligible targeted refinancing program, as defined under 12 CFR 1291.1; (2) such entities are operating under the conservatorship or receivership of the FHFA pursuant to section 1367 of the Federal Housing Enterprises Financial Safety and Soundness Act of 1992 (12 U.S.C. 4617(i)) on the date the refinancing is consummated; (3) the existing obligation satisfied and replaced by the refinancing is owned by Fannie Mae or Freddie Mac; (4) the existing obligation satisfied and replaced by the refinancing was not consummated on or after January 10, 2014; and (5) the refinancing was not consummated on or after January 10, 2021.

Proposed comment 43(a)(3)(viii)-1 would have explained that § 1026.43(a)(3)(viii) provides an exemption from the requirements of § 1026.43(c) through (f) for certain extensions of credit that are considered refinancings, as defined in § 1026.20(a) but without regard for whether the creditor is the creditor, holder, or servicer of the original obligation, that are eligible for purchase or guarantee by Fannie Mae or Freddie Mac. The comment would also have explained that the exemption provided by § 1026.43(a)(3)(viii) would be available only while these entities remain in conservatorship. The proposed comment also contained illustrative examples of this provision.

The Bureau expressed concern that unscrupulous creditors would be able to use the exemption to engage in loan-flipping or other harmful practices. Thus, the Bureau requested feedback on whether this exemption was generally appropriate. In particular, the Bureau requested feedback regarding whether consumers could be harmed by the proposed exemption and whether this exemption would ensure access to responsible and affordable refinancing credit. The Bureau also requested feedback regarding the reference to eligible targeted refinancing programs under proposed § 1026.43(a)(3)(viii)(A). Specifically, the Bureau requested

[149] *See, e.g.,* 12 CFR 1291.1; 74 FR 38514, 38516 (Aug. 4, 2009).

comment regarding whether it would be more appropriate to refer to another public method of identifying refinancing programs similar to HARP, and, if so, what method of public identification would be appropriate. The Bureau also solicited feedback regarding whether reference to a notice published by FHFA pursuant to 12 CFR 1253.3 or 1253.4 would facilitate compliance more effectively than the proposed reference in § 1026.43(a)(3)(viii)(A).

Comments Received

Many commenters supported the proposed exemption. Several industry commenters argued that the exemption was necessary to prevent the imposition of unnecessary costs on consumers. These commenters generally believed that the ability-to-repay requirements were too burdensome and that creditors would be forced to raise costs to comply with the regulations. One government-sponsored enterprise commenter argued that the exemption was necessary to preserve access to credit for consumers eligible for a refinancing under HARP. This commenter argued that many HARP loans would be subject to the rebuttable presumption of compliance, and that industry would refuse to make any loans that fell outside of the safe harbor for qualified mortgages. Several industry commenters and a Federal agency commenter argued that the Bureau's proposed reference to FHFA regulations was unnecessary. These commenters asserted that FHFA oversight was sufficient to ensure that consumers would not be harmed by creditors offering mortgage loans eligible for purchase or guarantee by the GSEs. For similar reasons, these commenters argued that the Bureau's proposed date on which the exemption would expire was unnecessary, as consumers would always benefit from a GSE-eligible refinancing, regardless of when the consumer's original loan was consummated or when the consumer obtained the refinancing. Finally, several industry commenters and a Federal agency commenter argued that limiting the refinancing exemption to HARP-eligible consumers was unnecessary, as all consumers could benefit from a GSE refinancing program and limiting the exemption to HARP-eligible consumers would impose needless costs on all other consumers. Some of these commenters also asked the Bureau to define eligible refinancings by reference to the Fannie Mae or Freddie Mac selling or servicing guides, and some asked the Bureau to expand the exemption to include refinancings eligible for non-GSE streamlined refinancing programs.

One consumer advocate commenter strongly opposed the proposed exemption. This commenter stressed that predatory refinancings were one of the primary causes of the financial crisis and that the ability-to-repay requirements were intended to protect consumers from the abusive equity-stripping practices that harmed so many consumers. This commenter stated that the proposed exemption would immunize creditors from TILA liability with respect to refinancings offered to some of the most vulnerable consumers, enabling unscrupulous creditors to engage in serial refinancings that harm consumers. This commenter also disputed the contention raised by others that the ability-to-repay requirements are costly and burdensome by asserting that the Bureau's provisions comprise basic underwriting requirements that all creditors should consider before extending refinancing credit. A State attorney general also opposed the proposed exemption for similar reasons. This commenter also argued that the proposed exemption would affect a large segment of the mortgage market, thereby potentially placing a large number of consumers at risk while undermining the Bureau's goal of providing uniform standards for the entire mortgage loan industry.

The Final Rule

The Bureau is withdrawing the proposed exemption for the reasons discussed below. Upon further review and consideration of the comments received, the Bureau has determined that the proposed exemption would be inappropriate. As discussed in the Bureau's proposal, the Bureau was concerned that the ability-to-repay requirements and qualified mortgage provisions would restrict access to credit for certain consumers seeking to obtain a refinancing. After performing additional analysis prompted by the comments received, the Bureau believes that the special qualified mortgage provision under § 1026.43(e)(4), which generally provides qualified mortgage status to GSE-eligible mortgage loans, including refinancings, strikes the appropriate balance between preserving consumers' rights to seek redress for violations of TILA and ensuring access to responsible, affordable credit during the current transition period.

The Bureau acknowledges that, under the qualified mortgage provision in § 1026.43(e)(4), a HARP loan would still need to meet certain minimum requirements imposed by the Dodd-Frank Act. To receive qualified mortgage status, in addition to GSE-eligibility, § 1026.43(e)(4)(i)(A) provides that a mortgage loan may not include the higher-risk loan terms identified in § 1026.43(e)(2)(i) (*e.g.,* negative amortization and interest-only payments), may not have a loan term that exceeds 30 years, and may not impose points and fees in excess of the thresholds in § 1026.43(e)(3). However, while some HARP refinancings may not be eligible for this qualified mortgage status, the Bureau does not believe that many HARP loans would fail to meet these minimum requirements. Currently, HARP refinancings generally may not contain the risky features identified in § 1026.43(e)(2)(i).[150] While, HARP programs permit refinancings that provide for loan terms in excess of 30 years, the Bureau does not believe that many consumers receive such loans.[151] Furthermore, while market-wide data regarding points and fees on HARP loans is not available, the Bureau does not believe that many HARP loans would provide for points and fees in excess of the § 1026.43(e)(3) thresholds. Refinancings are usually less complicated than purchase transactions. Therefore, refinancings generally require fewer costs, which makes it unlikely that a HARP loan would exceed the points and fees thresholds, and loans under this program would not likely be subject to some types of pricing abuses related to refinancings generally. In addition, the Bureau did not receive comment suggesting that points and fees on HARP loans exceed the § 1026.43(e)(3) thresholds. Importantly, as discussed in the 2013 ATR Final Rule, the Bureau believes that Congress intended for loans with these risky features, long loan terms, or high points and fees to be excluded from the scope of the qualified mortgage definition.[152] As the Bureau believes that few HARP loans would fail to meet these minimum statutory requirements, the Bureau does not believe that a

[150] As of April, 2013, HARP refinancings offered by Fannie Mae may not include negative amortization or interest-only features. *See* Fannie Mae, Single-Family Selling Guide, Chapter 5 (April 9, 2013), *available at https://www.fanniemae.com/content/guide/sel040913.pdf.* Freddie Mac does not offer mortgage loans with interest-only features and prohibits negative amortization on refinancings made under its HARP program. *See* Freddie Mac, Single-Family Seller/Servicer Guide, Vol. I, Chapters 22.4 and A24.3, *available at: http://www.freddiemac.com/sell/guide/.*

[151] Data on HARP loans with 40-year loan terms is not publicly available. *See* Federal Housing Finance Agency Refinance Report (June 2012), *available at: http://www.fhfa.gov/webfiles/25164/Feb13RefiReportFinal.pdf.*

[152] *See* 78 FR 6516–20 (Jan. 30, 2013).

modification is necessary to ensure access to responsible, affordable credit.

Although many commenters approved of the proposed exemption, these commenters generally did not address the costs and benefits of the proposed exemption in light of the special qualified mortgage status granted to GSE-eligible loans under the Bureau's January 2013 ATR Final Rule. For example, several commenters asserted that the ability-to-repay requirements were incompatible with HARP program requirements. However, given that GSE eligibility generally satisfies the requirements of § 1026.43(e)(4), the Bureau does not believe that the special qualified mortgage provisions are inconsistent with the requirements of HARP or similar programs. For the same reasons, the Bureau does not agree with the arguments advanced by several commenters that the ability-to-repay requirements would add costs that would make these programs unsustainable. These comments did not explain what additional costs would be imposed by the regulation beyond the costs creditors would incur in determining GSE eligibility, which would be required even in the absence of the Bureau's requirements. Based on the comments provided, the Bureau does not believe that the requirements of § 1026.43(e)(4) impose any additional meaningful costs on creditors. Thus, it does not appear that the ability-to-repay requirements would impair the effectiveness of programs such as HARP.

While one GSE commenter addressed the potential difference between the proposed exemption and the qualified mortgage provisions, the Bureau is not persuaded by the arguments that creditors would rather cease extending credit than make a qualified mortgage loan subject to the rebuttable presumption. As discussed above, as GSE eligibility generally satisfies the requirements of § 1026.43(e)(4), the Bureau does not believe that creditors making qualified mortgages would incur any meaningful additional risk by making mortgage loans pursuant to the eligibility requirements prescribed by GSEs. The Bureau believes that the ability-to-repay requirements and qualified mortgage provisions reflect standard industry underwriting practices, and that creditors that make a reasonable effort to determine a consumer's ability to repay would not be concerned with potential litigation risk that may result from the rebuttable presumption. Thus, based on the feedback provided, the Bureau does not believe that a creditor would incur much, if any, additional cost by extending refinancing credit under the qualified mortgage provisions of § 1026.43(e)(4) as opposed to the exemption under proposed § 1026.43(a)(3)(viii). Absent evidence that the special qualified mortgage provisions for GSE-eligible loans impose significant costs on creditors, the Bureau does not believe that consumers are at risk of being denied responsible, affordable mortgage credit.

On the other hand, there is a risk that consumers could be harmed by the proposed exemption. The Bureau is persuaded by the arguments that the proposed exemption could potentially enable unscrupulous creditors to harm consumers. The Bureau agrees that the ability-to-repay requirements were intended, in part, to prevent harmful practices such as equity-stripping. While the abuses of the past are seemingly absent from today's mortgage market, the Bureau does not believe it would be appropriate to deny consumers the means to seek redress for TILA violations. As discussed above, the § 1026.43(e)(4) qualified mortgage provision provides additional protection to consumers and preserves potential claims in the event of abuse. For higher-priced qualified mortgages, consumers will still have the ability to assert a claim under TILA section 130(a) and (k) and prove that, despite the presumption of compliance attached to the qualified mortgage, the creditor nonetheless failed to comply with the ability-to-repay requirements. Thus the cost to consumers of an exemption could be significant, as opposed to the relatively insignificant costs associated with complying with the special qualified mortgage provisions. Furthermore, given the detailed GSE eligibility requirements, the Bureau does not believe it is likely that a creditor operating a legitimate mortgage lending operation would face meaningful litigation risk by originating qualified mortgages, even those subject to the rebuttable presumption. The Bureau received no persuasive comments contradicting the Bureau's belief that the special qualified mortgage provisions of § 1026.43(e)(4) strikes the appropriate balance between consumer protection and the needs of the mortgage lending market during the current transition period. Absent persuasive evidence that the qualified mortgage provisions would endanger access to credit for the consumers addressed by the proposal, the Bureau does not believe that permitting this risk of consumer abuse is appropriate. Thus, the Bureau concludes that the proposed exemption is neither necessary nor proper, and proposed § 1026.43(a)(3)(viii) is withdrawn.

As discussed above, several industry commenters and a Federal agency commenter requested various modifications to the proposed language. For example, some commenters argued that the exemption should refer to the Fannie Mae or Freddie Mac selling guide, some commenters requested that the Bureau provide an exemption for all streamlined refinancing programs, and some commenters asked the Bureau to adopt the proposed exemption without the time limitations in proposed § 1026.43(a)(3)(viii)(D) and (E). As the Bureau has decided to withdraw proposed § 1026.43(a)(3)(viii), the issues addressed in these and similar comments are moot. As discussed above, mortgage loans made under a streamlined refinancing program are eligible for the temporary qualified mortgage status under § 1026.43(e)(4), provided the requirements of that paragraph are met.

43(b) Definitions

43(b)(4)

Background

TILA section 129C(a)(1) through (4) and the Bureau's rules thereunder, § 1026.43(c), prohibit a creditor from making a residential mortgage loan unless the creditor makes a reasonable, good faith determination, based on verified and documented information, that the consumer has a reasonable ability to repay the loan. TILA section 129C(b) provides a presumption of compliance with regard to these ability-to-repay requirements if a loan is a qualified mortgage. Creditors may view qualified mortgage status as important at least in part because TILA section 130(a) and (k) provide that, if a creditor fails to comply with the ability-to repay requirements, a consumer may be able to recover special statutory damages equal to the sum of all finance charges and fees paid within the first three years after consummation, among other damages and costs, and may be able to assert the creditor's failure to comply to obtain recoupment or setoff in a foreclosure action even after the statute of limitations for affirmative claims has passed. TILA section 129C(b)(3)(B)(i) authorizes the Bureau to prescribe regulations that revise, add to, or subtract from the criteria that define a qualified mortgage upon a finding that such regulations are, among other things, necessary or proper to ensure that responsible, affordable credit remains available to consumers in a manner consistent with the purposes of TILA section 129C.

Section 1026.43(e)(1) specifies the strength of presumption of compliance regardless of which regulatory definition of qualified mortgage applies. Under § 1026.43(e)(1)(i), a qualified mortgage that is not a higher-priced covered transaction as defined in § 1026.43(b)(4) is subject to a conclusive presumption of compliance, or safe harbor. In contrast, under § 1026.43(e)(1)(ii) a qualified mortgage that is a higher-priced covered transaction is subject to a rebuttable presumption of compliance.

Section 1026.43(b)(4) defines a higher-priced covered transaction to mean a transaction within the scope of § 1026.43 with an annual percentage rate that exceeds the average prime offer rate for a comparable transaction as of the date the interest rate is set by 1.5 or more percentage points for a first-lien covered transaction or by 3.5 or more percentage points for a subordinate-lien covered transaction. The average prime offer rates are published weekly by the Federal Financial Institutions Examination Council based on a national survey of creditors, the Freddie Mac Primary Mortgage Market Survey®. The average prime offer rates estimate the national average APR for first-lien mortgages offered to consumers with good credit histories and low-risk transaction features (*e.g.,* loan-to-value ratios of 80 percent or less). The higher-priced covered transaction thresholds generally conform to the thresholds for ''higher-priced mortgage loans'' under § 1026.35, which contains escrow requirements and other special protections adopted after the financial crisis for loans that have traditionally been considered subprime.

Section 1026.43(e) and (f) defines three categories of qualified mortgages. First, § 1026.43(e)(2) provides a general definition of a qualified mortgage. Second, § 1026.43(e)(4) provides that loans that are eligible to be purchased, guaranteed, or insured by certain government agencies or Fannie Mae or Freddie Mac are qualified mortgages, subject to certain restrictions including restrictions on product features and points and fees. Section 1026.43(e)(4) expires after seven years and may expire sooner with respect to some loans if other government agencies exercise their rulemaking authority under TILA section 129C or if Fannie Mae or Freddie Mac exit conservatorship.

Third, § 1026.43(f) provides that certain balloon-payment loans are qualified mortgages if they are made by a small creditor that:

- Had total assets less than $2 billion (adjusted annually for inflation) as of the end of the preceding calendar year;
- Together with all affiliates, extended 500 or fewer first-lien mortgages during the preceding calendar year; and
- Extended more than 50 percent of its total mortgages secured by properties that are in rural or underserved areas during the preceding calendar year.

Section 1026.43(f) includes only balloon-payment loans held in portfolio for at least three years by these small creditors, subject to certain exceptions. Further, it includes only loans that were not subject, at consummation, to a commitment to be acquired by any person other than another qualified small creditor.

As discussed in the section-by-section analysis of § 1026.43(e)(5) below, the Bureau proposed and is adopting an additional fourth category of qualified mortgages that includes certain loans originated and held in portfolio by small creditors. Like § 1026.43(f), § 1026.43(e)(5) includes loans originated and held in portfolio by creditors that had total assets less than $2 billion (adjusted annually for inflation) as of the end of the preceding calendar year and, together with all affiliates, extended 500 or fewer first-lien mortgages during the preceding calendar year. Unlike § 1026.43(f), new § 1026.43(e)(5) is not limited to creditors that operate predominantly in rural or underserved areas and does not include loans with a balloon payment.

Proposal Regarding Higher-Priced Covered Transactions

The Bureau proposed to amend the definition of higher-priced covered transaction in § 1026.43(b)(4) with respect to qualified mortgages that are originated and held in portfolio by small creditors as described in § 1026.43(e)(5) and with respect to balloon-payment qualified mortgages originated and held in portfolio by small creditors operating predominantly in rural or underserved areas as described in § 1026.43(f). The Bureau proposed to amend § 1026.43(b)(4) to provide that a first-lien loan that is a qualified mortgage under § 1026.43(e)(5) or (f) is a higher-priced covered transaction if the annual percentage rate exceeds APOR for a comparable transaction by 3.5 or more percentage points. This would have the effect of extending the qualified mortgage safe harbor described in § 1026.43(e)(1)(i) to first-lien loans that are qualified mortgages under § 1026.43(e)(5) or (f) that have an annual percentage rate between 1.5 and 3.5 percentage points above APOR. As discussed in more detail below, the Bureau understands that small creditors often charge higher rates and fees than larger creditors for reasons including their higher cost of funds. The Bureau proposed this amendment to § 1026.43(b)(4) because it believes that many loans made by small creditors will exceed the existing qualified mortgage safe harbor threshold. Without the proposed amendment to § 1026.43(b)(4), these loans would be considered higher-priced covered transactions and would fall under the rebuttable presumption of compliance described in § 1026.43(e)(1)(ii). The Bureau was concerned that small creditors would be less likely to make such loans due to concerns about liability risk, thereby reducing access to responsible credit.

Comments Received

The Bureau solicited comment on several issues related to the proposed amendments to § 1026.43(b)(4). First, the Bureau solicited comment regarding whether the proposed amendments to § 1026.43(b)(4) are necessary to preserve access to responsible, affordable mortgage credit and regarding any adverse effects the proposed amendments would have on consumers. Most commenters agreed that small creditors may charge more than larger creditors for legitimate business reasons; that amending the definition of higher-priced covered transaction for these types of qualified mortgages is necessary to preserve access to responsible, affordable mortgage credit; and that the rule would provide appropriate protection for consumers even with a higher interest rate threshold. Commenters expressing this view included some consumer advocacy organizations, coalitions of State regulators, national and State trade groups representing creditors, national and State mortgage bankers associations, a national association representing home builders, one very large creditor, and many small creditors.

A much smaller number of commenters opposed the proposed amendments. These included other consumer advocacy organizations, a trade group representing very large creditors, a national organization representing mortgage brokers, a letter submitted in substantially similar form by several individual mortgage brokers, and one very large creditor. These commenters generally argued that a consumer's ability to repay does not depend on the creditor's size and that the same standards therefore should apply to all creditors. One of these commenters argued that small creditors do not need to charge higher rates and fees because their higher costs are offset by lower default rates.

The Bureau also solicited comment on the proposed 3.5 percentage point threshold and whether another threshold would be more appropriate. While many commenters supported the proposed 3.5 percentage point threshold, several commenters argued that the proposed 3.5 percentage point threshold was not sufficient and should be raised. Commenters expressing this view included a national trade group representing creditors, State bankers associations, and several small creditors. These commenters generally suggested thresholds between 4.0 and 5.5 percentage points above APOR. Several of these commenters, including the national trade group, cited the traditional principle that small creditors generally must charge consumers 4.0 percentage points above the creditor's cost of funds in order to operate safely and soundly.

Finally, the Bureau solicited comment on whether, to preserve access to mortgage credit, the Bureau also should raise the threshold for subordinate-lien covered transactions that are qualified mortgages under § 1026.43(e)(5) and (f), and, if so, what threshold would be appropriate for those loans. A small number of commenters, including a State bankers association and several small creditors, urged the Bureau to adopt a higher threshold for subordinate-lien covered transactions. These commenters generally argued that subordinate-lien loans entail inherently greater credit risk and that a higher threshold was needed to account for this additional risk. Most commenters did not address the threshold for subordinate-lien loans.

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The amendments to § 1026.43(b)(4) are adopted as proposed. The Bureau believes the amendments are warranted to preserve access to responsible, affordable mortgage credit for some consumers, including consumers who do not qualify for conforming mortgage credit and consumers in rural and underserved areas, as described below.

As discussed above in part II.A, the Bureau understands that small creditors are a significant source of loans that do not conform to the requirements for government guarantee and insurance programs or purchase by entities such as Fannie Mae and Freddie Mac. The Bureau also understands that larger creditors may be unwilling to make at least some of these loans because the consumers or properties involved cannot be accurately assessed using the standardized underwriting criteria employed by larger creditors or are illiquid because they are non-conforming and therefore entail greater risk. For similar reasons, the Bureau understands that larger creditors may be unwilling to purchase such loans. Small creditors often are willing to evaluate the merits of unique consumers and properties using flexible underwriting criteria and make highly individualized underwriting decisions. Small creditors often hold these loans on their balance sheets, retaining the associated credit, liquidity, and other risks.

The Bureau also understands that small creditors are a significant source of credit in rural and underserved areas. As discussed above in part II.A, small creditors are significantly more likely than larger creditors to operate offices in rural areas, and there are hundreds of counties nationwide where the only creditors are small creditors and hundreds more where larger creditors have only a limited presence.

The Bureau also understands that small creditors, including those operating in rural and underserved areas, may charge consumers higher interest rates and fees than larger creditors for several legitimate business reasons. As discussed above in part II.A, small creditors may pay more for funds than larger creditors. Small creditors generally rely heavily on deposits to fund lending activities and therefore pay more in expenses per dollar of revenue as interest rates fall and the spread between loan yields and deposit costs narrows. Small creditors also may rely more on interest income than larger creditors, as larger creditors obtain higher percentages of their income from noninterest sources such as trading, investment banking, and fiduciary services.

In addition, small creditors may find it more difficult to limit their exposure to interest rate risk than larger creditors and therefore may charge higher rates to compensate for that exposure. Similarly, any individual loan poses a proportionally more significant credit risk to a smaller creditor than to a larger creditor, and small creditors may charge higher rates or fees to compensate for that risk. Consumers obtaining loans that cannot readily be sold into the securitization markets also may pay higher interest rates and fees to compensate for the risk associated with the illiquidity of such loans.

Small creditors, including those operating in rural and underserved areas, have repeatedly asserted to the Bureau and to other regulators that they are unable or unwilling to assume the risk of litigation associated with lending outside the qualified mortgage safe harbor. The Bureau does not believe that the regulatory requirement to make a reasonable and good faith determination based on verified and documented evidence that a consumer has a reasonable ability to repay would entail significant litigation risk for small creditors, especially where their loan meets a qualified mortgage definition and qualifies for a rebuttable presumption of compliance. As discussed in part II.A above, small creditors as a group have consistently experienced lower credit losses for residential mortgage loans than larger creditors. The Bureau believes this is strong evidence that small creditors have historically engaged in responsible mortgage underwriting that includes considered determinations of consumers' ability to repay, at least in part because they bear the risk of default associated with loans held in their portfolios. The Bureau also believes that because many small creditors use a lending model based on maintaining ongoing relationships with their customers and have specialized knowledge of the community in which they operate, they therefore may have a more comprehensive understanding of their customers' financial circumstances and may be better able to assess ability to repay than larger creditors. In addition, the Bureau believes that small creditors operating in limited geographical areas may face significant risk of harm to their reputation within their community if they make loans that consumers cannot repay. At the same time, because of the relationship small creditors have with their customers, the Bureau believes that the likelihood of litigation between a customer and his or her community bank or credit union is low.

However, the Bureau acknowledges that due to their size small creditors may find even a remote prospect of litigation risk to be so daunting that they may change their business models to avoid it. The Bureau also believes that the exit of small creditors from the residential mortgage market could create substantial short-term access to credit issues.

The Bureau continues to believe that raising the interest rate threshold as proposed is necessary and appropriate to preserve access to responsible, affordable credit for consumers that are unable to obtain loans from other creditors because they do not qualify for conforming loans or because they live in rural or underserved areas. The existing qualified mortgage safe harbor applies to first-lien loans only if the annual percentage rate is less than 1.5 percentage points above APOR for comparable transactions. The Bureau believes that many loans made by small

creditors, including those operating in rural and underserved areas, will exceed that threshold but will not pose risks to consumers. These small creditors have repeatedly asserted to the Bureau and other regulators that they will not continue to extend mortgage credit unless they can make loans that are covered by the qualified mortgage safe harbor. The Bureau therefore believes that, unless § 1026.43(b)(4) is amended as proposed, small creditors operating in rural and underserved areas may reduce the number of mortgage loans they make or stop making mortgage loans altogether, limiting the availability of nonconforming mortgage credit and of mortgage credit in rural and underserved areas.

The Bureau is sensitive to concerns about the consistency of protections for all consumers and about maintaining a level playing field for market participants, but believes that a differentiated approach is justified here. The commenters who suggested that consumers' interests are best served by subjecting all creditors to the same standards provided nothing substantive that refutes the points raised in the Bureau's proposal regarding the lending track records and business models of small creditors, their concerns about litigation risk and compliance burden, and the potential access to credit problems the Bureau believes will arise if § 1026.43(b)(4) is not amended. For example, these commenters have not indicated that large creditors would be able and willing to fulfill the role currently played by small creditors in providing access to responsible, affordable nonconforming credit or credit in rural and underserved areas, nor have they provided evidence that the Bureau's concerns about limitations on access to credit if the interest rate threshold is not raised are unfounded. One commenter asserted that small creditors' lower credit losses are sufficient to offset their higher costs, making it unnecessary to raise the interest rate threshold. While the Bureau understands that small creditors have historically had lower credit losses, this commenter provided no evidence that these lower losses are sufficient to offset small creditors' higher cost of funds and greater reliance on interest income and the greater risks associated with holding loans in a comparatively small portfolio, and the Bureau is not aware of any such evidence.[153] In addition, these commenters have provided no evidence to challenge the Bureau's view, as described in the proposal, above, and in the section-by-section analysis of § 1026.43(e)(5) below, that the combination of the small creditors' relationship lending model, local knowledge, and other characteristics and the inherent incentives of portfolio lending are sufficient to protect consumers.

The Bureau does not believe, however, that it is necessary to raise the threshold for first-lien covered transactions above APOR plus 3.5 percentage points for either first-lien or subordinate-lien loans as suggested by some commenters. The Bureau estimated the average cost of funds for small creditors from publicly available call reports filed by small creditors between 2000 and 2012. These estimates suggest that the majority of first-lien mortgage loans priced by a small creditor at the creditor's cost of funds plus 4.0 percentage points, the traditional principle of small creditor safe and sound lending noted by several commenters, would fall below even the original threshold of APOR plus 1.5 percentage points. However, the Bureau acknowledges that its estimates are averages that do not reflect individual or regional differences in cost of funds and do not reflect the additional credit risk associated with subordinate-lien loans. The Bureau believes that the additional 2.0 percentage points afforded by the APOR plus 3.5 percentage point standard are sufficient to address these differences. The Bureau therefore believes that amending § 1026.43(b)(4) as proposed will allow small creditors to lend at a sustainable rate and still fall within the qualified mortgage safe harbor, thereby preserving access to affordable, responsible credit.

As discussed below in the section-by-section analysis of § 1026.43(e)(6), the Bureau is providing a two-year transition period during which small creditors may make balloon-payment qualified mortgages regardless of whether they operate predominantly in rural or underserved areas. The Bureau therefore is amending § 1026.43(b)(4) to include references to § 1026.43(e)(6) and to provide that a first-lien loan that is a qualified mortgage under § 1026.43(e)(6) is a higher priced covered transaction if the annual percentage rate exceeds APOR for a comparable transaction by 3.5 or more percentage points. This provision would apply to the same creditors and loans as § 1026.43(e)(5) and (f). The Bureau therefore believes that the rationales regarding raising the interest rate threshold for qualified mortgages under § 1026.43(e)(5) and (f) described above apply with equal force to qualified mortgages under this new provision.

Accordingly, the Bureau is exercising its authority under TILA sections 105(a) to amend § 1026.43(b)(4) substantially as proposed, with conforming amendments as described above. Pursuant to TILA section 105(a) the Bureau generally may prescribe regulations that provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary or proper to effectuate the purposes of TILA, among other things. In the 2013 ATR Final Rule the Bureau stated that it interpreted TILA section 129C(b)(1) to create a rebuttable presumption for qualified mortgages generally and exercised its adjustment authority under TILA 105(a) with respect to prime loans (loans with an APR that do not exceed APOR by 1.5 percentage points for first liens and 3.5 percentage points for second liens), to provide a conclusive presumption (*e.g.,* safe harbor).[154] In this final rule the Bureau uses its TILA section 105(a) adjustment authority to further expand the safe harbor to include certain covered transactions (those subject to the qualified mortgage definition under paragraph (e)(5), (e)(6) or (f)) that have an APR that exceeds the prime offer rate for a comparable transaction as of the date the interest rate is set by 3.5 percentage points for a first-lien covered transaction.

The Bureau believes that this adjustment to also provide a safe harbor for these loans is necessary and proper to facilitate compliance with and to effectuate the purposes of TILA, including to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans.[155] As

[153] The FDIC Community Banking Study, to which the Bureau has referred as authority for the point that small creditors have historically incurred lower credit losses than larger creditors, indicates that despite their lower credit losses and lower non-interest expenses, community banks on average have lower (worse) pre-tax return on assets and a higher and increasing (worse and deteriorating) ratio of noninterest expense to net operating revenue than noncommunity banks. The study attributes these in large part to community banks' reliance on interest income and the narrowing of the spread between asset yields and funding costs due to a prolonged period of historically low interest rates. *FDIC Community Banking Study,* p. IV–V, 4–1–4–11. *See also GAO Community Banks and Credit Unions Report,* p. 10–11.

[154] *See* 78 FR 6514.

[155] These adjustments are also consistent with the Bureau's authority under TILA section 129C(b)(3)(B)(i) to prescribe regulations that revise, add to, or subtract from the criteria that define a qualified mortgage upon a finding that such regulations are necessary or proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with

Continued

described above, the Bureau believes that, unless § 1026.43(b)(4) is amended, small creditors will be less likely to make residential mortgage loans. Because small creditors are a significant source of nonconforming mortgage credit and mortgage credit generally in rural or underserved areas, this would significantly limit access to mortgage credit for some consumers. The Bureau also believes that the relationship lending model, qualitative local knowledge, and size of small creditors, combined with the intrinsic incentives of portfolio lending, provide strong assurances that these creditors will make reasonable and good faith determinations of consumers' ability to repay. Providing a safe harbor for these loans facilitates compliance with the ability-to-repay standards in a manner consistent with the purposes of TILA.

43(e) Qualified Mortgages

43(e)(1) Safe Harbor and Presumption of Compliance

The Bureau is adopting two additional provisions regarding qualified mortgages, as discussed in the section-by-section analyses of § 1026.43(e)(5) and (6) below. The Bureau therefore is adopting conforming changes to § 1026.43(e)(1) to include references to these new provisions. Like other qualified mortgages, qualified mortgages under § 1026.43(e)(5) and (6) are covered by the safe harbor described in § 1026.43(e)(1)(i) if they are not higher-priced covered transactions and are subject to the rebuttable presumption of compliance described in § 1026.43(e)(1)(ii) if they are higher-priced covered transactions. However, the Bureau is adopting a different definition of higher-priced covered transaction to first-lien qualified mortgages under § 1026.43(e)(5) and (6). The section-by-section analysis of § 1026.43(b)(4), above, describes the alternate definition of higher-priced covered transactions.

43(e)(2) Qualified Mortgage Defined—General

The Bureau is adopting conforming amendments to § 1026.43(e)(2) to include references to § 1026.43(e)(5) and (6), as described in the section-by-section analyses of those sections, below.

43(e)(5) Qualified Mortgage Defined—Small Creditor Portfolio Loans

Background

TILA section 129C(a)(1) through (4) and the Bureau's rules thereunder, § 1026.43(c), prohibit a creditor from making a residential mortgage loan unless the creditor makes a reasonable, good faith determination, based on verified and documented information, that the consumer has a reasonable ability to repay the loan. TILA section 129C(b) provides that a creditor or assignee may presume that a loan has met the ability-to-repay requirements if a loan is a qualified mortgage. Creditors may view qualified mortgage status as important at least in part because TILA section 130 provides that, if a creditor fails to comply with the ability-to-repay requirements, a consumer may be able to recover special statutory damages equal to the sum of all finance charges and fees paid within the first three years after consummation, among other damages and costs, and may be able to assert the creditor's failure to comply to obtain recoupment or setoff in a foreclosure action even after the statute of limitations on affirmative claims has expired. TILA section 129C(b)(2)(A)(vi) authorizes, but does not require, the Bureau to establish limits on debt-to-income ratio or other measures of a consumer's ability to pay regular expenses after making payments on mortgage and other debts. TILA section 129C(b)(3)(B)(i) authorizes the Bureau to revise, add to, or subtract from the criteria that define a qualified mortgage upon a finding that such regulations are, among other things, necessary or proper to ensure that responsible, affordable credit remains available to consumers in a manner consistent with the purposes of TILA section 129C or necessary and appropriate to effectuate the purposes of TILA sections 129B and 129C.

Section 1026.43(e) and (f) defines three categories of qualified mortgages. First, § 1026.43(e)(2) prescribes the general definition of a qualified mortgage. Second, § 1026.43(e)(4) provides that certain loans that are eligible to be purchased, guaranteed, or insured by certain Federal government agencies or Fannie Mae or Freddie Mac while operating under conservatorship are qualified mortgages. Section 1026.43(e)(4) expires seven years after its effective date and may expire earlier with respect to certain loans if other Federal government agencies exercise their rulemaking authority under TILA section 129C or if the GSEs exit conservatorship. Third, § 1026.43(f) provides that certain loans with a balloon payment made by small creditors operating predominantly in rural or underserved areas are qualified mortgages.

The Bureau's Proposal

The Bureau proposed to define a fourth category of qualified mortgages including loans originated and held in portfolio by certain small creditors in new § 1026.43(e)(5). This additional category of qualified mortgages would have been similar in several respects to § 1026.43(f), which provides that certain balloon loans made by small creditors operating predominantly in rural or underserved areas are qualified mortgages. As under § 1026.43(f), the additional category would have included loans originated by small creditors, as defined by asset-size and transaction thresholds, and held in portfolio by those creditors for at least three years, subject to certain exceptions. However, proposed § 1026.43(e)(5) would have included small creditors that do not operate predominantly in rural or underserved areas and would not have included loans with a balloon payment.

Specifically, the new category would have included certain loans originated by creditors that:

- Have total assets that do not exceed $2 billion as of the end of the preceding calendar year (adjusted annually for inflation); and
- Together with all affiliates, extended 500 or fewer first-lien mortgages during the preceding calendar year.

The proposed additional category would have included only loans held in portfolio by these creditors. Specifically, proposed § 1026.43(e)(5) would have provided that a loan would lose its qualified mortgage status under § 1026.43(e)(5) if it is sold, assigned, or otherwise transferred, subject to exceptions for transfers that are made three or more years after consummation, to another qualifying institution, as required by a supervisory action, or pursuant to a merger or acquisition. In addition, proposed § 1026.43(e)(5) would have provided that a loan must not be subject at consummation to a commitment to be acquired by any person other than a person that also meets the above asset and origination criteria.

The loan also would have had to conform to all of the requirements under the § 1026.43(e)(2) general definition of a qualified mortgage except with regard to debt-to-income ratio. In other words, the loan could not have:

- Negative-amortization, interest-only, or balloon-payment features;
- A term longer than 30 years; or

the purposes of this section, necessary and appropriate to effectuate the purposes of TILA section 129B and section 129C, to prevent circumvention or evasion thereof, or to facilitate compliance with such section.

• Points and fees greater than 3 percent of the total loan amount (or, for smaller loans, a specified amount).

When underwriting the loan the creditor would have been required to take into account the monthly payment for any mortgage-related obligations, and:

• Use the maximum interest rate that may apply during the first five years and periodic payments of principal and interest that will repay the full principal;

• Consider and verify the consumer's current and reasonably expected income or assets other than the value of the property securing the loan; and

• Consider and verify the consumer's current debt obligations, alimony, and child support.

The creditor also would have been required to consider the consumer's debt-to-income ratio or residual income and to verify the underlying information generally in accordance with § 1026.43(c)(7). Section 1026.43(c)(7) describes how creditors must calculate a consumers' debt-to-income ratio or residual income for purposes of complying with the ability-to-repay rules set forth in § 1026.43(c). Section 1026.43(c)(7) specifies that a creditor must consider the ratio of or difference between a consumer's total monthly debt obligations and total monthly income. Section 1026.43(c)(7)(i)(A) specifies that a consumer's total monthly debt obligations includes the payment on the covered transaction as calculated according to § 1026.43(c)(5). However, for purposes of § 1026.43(e)(5), the calculation of the payment on the covered transaction must be determined in accordance with § 1026.43(e)(2)(iv) instead of § 1026.43(c)(5).

In contrast, the general definition of a qualified mortgage in § 1026.43(e)(2) requires a creditor to calculate the consumer's debt-to-income ratio according to instructions in appendix Q [156] and specifies that the consumer's debt-to-income ratio must be 43 percent or less.

As with all qualified mortgages, a qualified mortgage under § 1026.43(e)(5) would have received either a rebuttable presumption of compliance with, or a safe harbor from liability for violating, the ability-to-repay requirements in § 1026.43(c), depending on the annual percentage rate. However, as described above in the section-by-section analysis of § 1026.43(b)(4), the Bureau also proposed and is adopting an alternate definition of higher-priced covered transaction for first-lien covered transactions that are qualified mortgages under proposed § 1026.43(e)(5). Amended as proposed, § 1026.43(b)(4) provides that a first-lien covered transaction that is a qualified mortgage under proposed § 1026.43(e)(5) is a higher-priced covered transaction if the annual percentage rate exceeds APOR for a comparable transaction by 3.5 or more percentage points. This extends the qualified mortgage safe harbor described in § 1026.43(e)(1)(i) to first-lien qualified mortgages defined under proposed § 1026.43(e)(5) even if those loans have annual percentage rates between 1.5 and 3.5 percentage points higher than APOR. Without the amendment to § 1026.43(b)(4), such loans would have been covered by the rebuttable presumption of compliance described in § 1026.43(e)(1)(ii).

The Bureau proposed ten comments to clarify the requirements described in proposed § 1026.43(e)(5). Proposed comment 43(e)(5)–1 would have provided additional guidance regarding the requirement to comply with the general definition of a qualified mortgage under § 1026.43(e)(2). The proposed comment would have restated the regulatory requirement that a covered transaction must satisfy the requirements of the § 1026.43(e)(2) general definition of qualified mortgage, except with regard to debt-to-income ratio, to be a qualified mortgage under § 1026.43(e)(5). As an example, the proposed comment would have explained that a qualified mortgage under § 1026.43(e)(5) may not have a loan term in excess of 30 years because longer terms are prohibited for qualified mortgages under § 1026.43(e)(2)(ii). As another example, the proposed comment would have explained that a qualified mortgage under § 1026.43(e)(5) may not result in a balloon payment because § 1026.43(e)(2)(i)(C) provides that qualified mortgages may not have balloon payments except as provided under § 1026.43(f). Finally, the proposed comment would have clarified that a covered transaction may be a qualified mortgage under § 1026.43(e)(5) even though the consumer's monthly debt-to-income ratio exceeds 43 percent, § 1026.43(e)(2)(vi) notwithstanding.

Proposed comment 43(e)(5)–2 would have clarified that § 1026.43(e)(5) does not prescribe a specific monthly debt-to-income ratio with which creditors must comply. Instead, creditors must consider a consumer's debt-to-income ratio or residual income calculated generally in accordance with § 1026.43(c)(7) and verify the information used to calculate the debt-to-income ratio or residual income in accordance with § 1026.43(c)(3) and (4). The proposed comment would have explained that § 1026.43(c)(7) refers creditors to § 1026.43(c)(5) for instructions on calculating the payment on the covered transaction and that § 1026.43(c)(5) requires creditors to calculate the payment differently than § 1026.43(e)(2)(iv). The proposed comment would have clarified that, for purposes of the qualified mortgage definition in § 1026.43(e)(5), creditors must base their calculation of the consumer's debt-to-income ratio or residual income on the payment on the covered transaction calculated according to § 1026.43(e)(2)(iv) instead of according to § 1026.43(c)(5). Finally, the proposed comment would have clarified that creditors are not required to calculate the consumer's monthly debt-to-income ratio in accordance with appendix Q as is required under the general definition of qualified mortgages by § 1026.43(e)(2)(vi).

Proposed comment 43(e)(5)–3 would have noted that the term ''forward commitment'' is sometimes used to describe a situation where a creditor originates a mortgage loan that will be transferred or sold to a purchaser pursuant to an agreement that has been entered into at or before the time the transaction is consummated. The proposed comment would have clarified that a mortgage that will be acquired by a purchaser pursuant to a forward commitment does not satisfy the requirements of § 1026.43(e)(5), whether the forward commitment provides for the purchase and sale of the specific transaction or for the purchase and sale of transactions with certain prescribed criteria that the transaction meets. However, the proposed comment also would have clarified that a forward commitment to another person that also meets the requirements of § 1026.43(e)(5)(i)(D) is permitted. The proposed comment would have given the following example: Assume a creditor that is eligible to make qualified mortgages under § 1026.43(e)(5) makes a mortgage. If that mortgage meets the purchase criteria of an investor with which the creditor has an agreement to sell such loans after consummation, then the loan does not meet the definition of a qualified mortgage under § 1026.43(e)(5). However, if the investor meets the requirements of § 1026.43(e)(5)(i)(D), the mortgage will be a qualified mortgage if all other applicable criteria also are satisfied.

Proposed comment 43(e)(5)–4 would have reiterated that, to be eligible to make qualified mortgages under

[156] The Bureau has proposed certain revisions to Appendix Q. *See* 78 FR 25638–25662 (May 2, 2013). Comments on this proposal must be received on or before June 3, 2013.

§ 1026.43(e)(5), a creditor must satisfy the requirements of § 1026.35(b)(2)(iii)(B) and (C). For ease of reference, the comment would have stated that § 1026.35(b)(2)(iii)(B) requires that, during the preceding calendar year, the creditor and its affiliates together originated 500 or fewer first-lien covered transactions and that § 1026.35(b)(2)(iii)(C) requires that, as of the end of the preceding calendar year, the creditor had total assets of less than $2 billion, adjusted annually for inflation.

Proposed comment 43(e)(5)–5 would have clarified that creditors generally must hold a loan in portfolio to maintain the transaction's status as a qualified mortgage under § 1026.43(e)(5), subject to four exceptions. The proposed comment would have clarified that, unless one of these exceptions applies, a loan is no longer a qualified mortgage under § 1026.43(e)(5) once legal title to the debt obligation is sold, assigned, or otherwise transferred to another person. Accordingly, unless one of the exceptions applies, the transferee could not benefit from the presumption of compliance for qualified mortgages under § 1026.43(e)(1) unless the loan also met the requirements of another qualified mortgage definition. Proposed comment 43(e)(5)–6 would have clarified that § 1026.43(e)(5)(ii) applies not only to an initial sale, assignment, or other transfer by the originating creditor but to subsequent sales, assignments, and other transfers as well. The proposed comment would have given the following example: Assume Creditor A originates a qualified mortgage under § 1026.43(e)(5). Six months after consummation, Creditor A sells the qualified mortgage to Creditor B pursuant to § 1026.43(e)(5)(ii)(B) and the loan retains its qualified mortgage status because Creditor B complies with the limits on asset size and number of transactions. If Creditor B sells the qualified mortgage, it will lose its qualified mortgage status under § 1026.43(e)(5) unless the sale qualifies for one of the § 1026.43(e)(5)(ii) exceptions for sales three or more years after consummation, to another qualifying institution, as required by supervisory action, or pursuant to a merger or acquisition.

Proposed comment 43(e)(5)–7 would have clarified that, under § 1026.43(e)(5)(ii)(A), if a qualified mortgage under § 1026.43(e)(5) is sold, assigned, or otherwise transferred three years or more after consummation, the loan retains its status as a qualified mortgage under § 1026.43(e)(5) following the transfer. The proposed comment would have clarified that this is true even if the transferee is not itself eligible to originate qualified mortgages under § 1026.43(e)(5). The proposed comment would have clarified that, once three or more years after consummation have passed, the qualified mortgage will continue to be a qualified mortgage throughout its life, and a transferee, and any subsequent transferees, may invoke the presumption of compliance for qualified mortgages under § 1026.43(e)(1).

Proposed comment 43(e)(5)–8 would have clarified that, under § 1026.43(e)(5)(ii)(B), a qualified mortgage under § 1026.43(e)(5) may be sold, assigned, or otherwise transferred at any time to another creditor that meets the requirements of § 1026.43(e)(5)(v). The proposed comment would have noted that section § 1026.43(e)(5)(v) requires that a creditor, together with all affiliates during the preceding calendar year, originated 500 or fewer first-lien covered transactions and had total assets less than $2 billion (adjusted annually for inflation) at the end of the preceding calendar year. The proposed comment would have clarified that a qualified mortgage under § 1026.43(e)(5) that is transferred to a creditor that meets these criteria would retain its qualified mortgage status even if it is transferred less than three years after consummation.

Proposed comment 43(e)(5)–9 would have clarified that § 1026.43(e)(5)(ii)(C) facilitates sales that are deemed necessary by supervisory agencies to revive troubled creditors and resolve failed creditors. The proposed comment would have noted that this section provides that a qualified mortgage under § 1026.43(e)(5) retains its qualified mortgage status if it is sold, assigned, or otherwise transferred to: another person pursuant to a capital restoration plan or other action under 12 U.S.C. 1831o; the actions or instructions of any person acting as conservator, receiver or bankruptcy trustee; an order of a State or Federal government agency with jurisdiction to examine the creditor pursuant to State or Federal law; or an agreement between the creditor and such an agency. The proposed comment would have clarified that a qualified mortgage under § 1026.43(e)(5) that is sold, assigned, or otherwise transferred under these circumstances retains its qualified mortgage status regardless of how long after consummation it is sold and regardless of the size or other characteristics of the transferee. The proposed comment also would have clarified that § 1026.43(e)(5)(ii)(C) does not apply to transfers done to comply with a generally applicable regulation with future effect designed to implement, interpret, or prescribe law or policy in the absence of a specific order by or a specific agreement with a government agency described in § 1026.43(e)(5)(ii)(C) mandating the sale of one or more qualified mortgages under § 1026.43(e)(5) held by the creditor, or one of the other circumstances listed in § 1026.43(e)(5)(ii)(C). As an example, the proposed comment would have explained that a qualified mortgage under § 1026.43(e)(5) that is sold pursuant to a capital restoration plan under 12 U.S.C. 1831o would retain its status as a qualified mortgage following the sale. However, if the creditor simply chose to sell the same qualified mortgage as one way to comply with general regulatory capital requirements in the absence of supervisory action or agreement, the mortgage would lose its status as a qualified mortgage following the sale unless it qualifies under another definition of qualified mortgage.

Proposed comment 43(e)(5)–10 would have clarified that a qualified mortgage under § 1026.43(e)(5) retains its qualified mortgage status if a creditor merges with or is acquired by another person regardless of whether the creditor or its successor is eligible to originate new qualified mortgages under § 1026.43(e)(5) after the merger or acquisition. However, the proposed comment also would have clarified that the creditor or its successor can originate new qualified mortgages under § 1026.43(e)(5) after the merger or acquisition only if the creditor or its successor complies with all of the requirements of § 1026.43(e)(5) at that time. The proposed comment would have provided the following example: Assume a creditor that originates 250 covered transactions each year and originates qualified mortgages under § 1026.43(e)(5) is acquired by a larger creditor that originates 10,000 covered transactions each year. Following the acquisition, the small creditor would no longer be able to originate § 1026.43(e)(5) qualified mortgages because, together with its affiliates, it would originate more than 500 covered transactions each year. However, the § 1026.43(e)(5) qualified mortgages originated by the small creditor before the acquisition would retain their qualified mortgage status.

Comments Received

A large number and broad range of commenters expressed support for proposed § 1026.43(e)(5). These commenters included national, State, and regional trade groups representing

banks and credit unions, more than 90 small and mid-size creditors from more than two dozen States, one very large creditor, coalitions of State regulators, consumer advocacy organizations, a national trade group representing mortgage bankers, national trade groups representing homebuilders and real estate agents, a tribally designated housing entity, and representatives of the manufactured housing industry. These commenters generally agreed with the points made by the Bureau in its proposal.

A much smaller number of commenters objected to proposed § 1026.43(e)(5). These creditors included a consumer advocacy organization, a national trade group representing very large creditors, one very large creditor, a national trade group representing mortgage brokers, and several individual mortgage brokers. These commenters generally argued that the Bureau should not adopt special rules for small creditors because a consumer's ability to repay does not depend on the size of the creditor. These commenters also raised other arguments, such as that proposed § 1026.43(e)(5) would encourage regulatory arbitrage and charter shopping by creditors or that the Bureau's proposal to provide an additional qualified mortgage definition is evidence that the ability-to-repay and qualified mortgage provisions of the Dodd-Frank Act are fundamentally flawed and should be abandoned in favor of further study.

The Bureau solicited comments on a number of specific issues related to proposed § 1026.43(e)(5). First, the Bureau solicited comment on whether non-conforming mortgage credit is likely to be unavailable if the rule is not amended and whether amending the rule as proposed would ensure that such credit is made available in a responsible, affordable way. Commenters supporting proposed § 1026.43(e)(5) generally agreed with the Bureau's assessment that, without amendment, the ability-to-repay and qualified mortgage rules would significantly limit access to nonconforming credit and access to credit in rural and underserved areas. Many individual small creditors asserted that they would limit the number of residential mortgage loans they made or cease mortgage lending altogether if the rule was not amended and that this would severely limit access to credit in their communities. National and State trade groups representing creditors expressed similar views on behalf of their members. These commenters generally agreed that small creditors are uniquely able and have strong incentives to make accurate determinations of ability to repay, that the incentives to make these determinations accurately and conservatively are particularly strong with respect to portfolio loans, and that the combination of these factors would provide ample protection for consumers. Commenters opposing proposed § 1026.43(e)(5) did not refute the points raised by the Bureau in the proposal. These commenters did not offer evidence or substantive arguments that access to credit would be preserved without the proposed amendments, did not suggest meaningful alternative ways of preserving access to credit, and did not offer substantive arguments or evidence that credit made available pursuant to proposed § 1026.43(e)(5) likely would be irresponsible or unaffordable. One commenter argued that proposed § 1026.43(e)(5) would not preserve access to credit because it would not provide significant regulatory relief to small creditors and because it was limited to a small number of loans per small creditor and therefore would not benefit consumers.

Second, the Bureau solicited comment on the following issues relating to the criteria describing small creditors: Whether the Bureau should adopt criteria consistent with those used in § 1026.35(b) and in the § 1026.43(f) definition of qualified mortgages which applies to certain balloon loans made by small creditors operating predominantly in rural or underserved areas; whether the proposed $2 billion asset limit is appropriate and whether the limit should be higher or lower; and whether to include a limitation on the number of first-lien covered transactions extended by the creditor and its affiliates and, if so, whether the proposed 500-transaction limit is appropriate.

Most commenters urged the Bureau to expand the scope of proposed § 1026.43(e)(5) by adjusting the asset or originations limits or both.[157] Many commenters, including national and State trade groups representing banks and credit unions and many individual small creditors, asserted that 500 annual first-lien originations is more typical of a creditor with assets of $500 million than a creditor with assets of $2 billion. These commenters argued that the 500 annual first-lien originations limit is significantly more restrictive than the $2 billion asset limit and should therefore either be raised or be eliminated. Commenters suggested alternate limits such as 1,000 portfolio loans or between 2,000 and 5,000 total first-lien originations. Some commenters, including trade groups representing creditors and individual small and mid-size creditors, urged the Bureau to raise the $2 billion asset limit to $5 billion or $10 billion. These commenters argued that this change is necessary to facilitate access to nonconforming credit and access to credit in areas that are served only by mid-sized banks with assets greater than $2 billion.

Third, the Bureau solicited comment regarding the requirement that loans be held in portfolio generally, including whether the proposed exemptions were appropriate and whether other criteria, guidance, or exemptions should be included regarding the requirement to hold loans in portfolio, either in lieu of or in addition to those included in the proposal. Commenters generally did not object to the requirement that loans be held in portfolio as described in proposed § 1026.43(e)(5) and the accompanying comments. In addition, many commenters agreed with the Bureau that the requirement that loans be held in portfolio provides important protections for consumers because it aligns consumers' and creditors' interests regarding ability to repay. One commenter, a consumer advocacy organization, argued against the proposed provision allowing loans to be transferred less than three years after origination because of a creditor's bankruptcy or failure. This commenter argued that bankruptcy or failure may be indicative of poor underwriting leading to high default rates and that consumers therefore should retain the right to make claims against the creditor in bankruptcy, conservatorship, or receivership.

Fourth, the Bureau solicited comment on the loan feature and underwriting requirements with which qualified mortgages under proposed § 1026.43(e)(5) would have to comply. The Bureau solicited comment on whether qualified mortgages under proposed § 1026.43(e)(5) should be exempt from additional provisions of § 1026.43(e)(2) or should be subject to any other loan feature or underwriting requirements, either in lieu of or in addition to those proposed. In particular, the Bureau solicited comment on whether these qualified mortgages should be exempt from the requirement to consider debt-to-income

[157] Several commenters, including representatives of creditors that finance manufactured housing and two creditors that provide low-documentation mortgage loans predominantly to Asian immigrants in California, argued that the Bureau should adopt additional qualified mortgage definitions that would include their mortgage loan products. The Bureau did not propose and did not solicit comment regarding such additional qualified mortgage definitions and is not adopting such definitions at this time.

ratio calculated according to appendix Q and the prohibition on debt-to-income ratios in excess of 43 percent and whether other requirements related to debt-to-income ratio or residual income should be provided, either in lieu of or in addition to those proposed. Most commenters supported relaxing underwriting restrictions on portfolio loans made by small creditors generally and exempting these loans from both the requirement to consider debt-to-income ratio calculated according to appendix Q and the prohibition on debt-to-income ratios in excess of 43 percent specifically.[158] These commenters, including consumer advocacy organizations, national and State trade groups representing banks and credit unions, and many small creditors, agreed that small creditors are particularly able to make accurate determinations of ability to repay without a specific numeric limit and that the requirement to calculate debt-to-income ratio according to appendix Q would present a significant burden to many small creditors with little or no corresponding benefit to consumers. In addition, many small creditors and national and State trade groups representing creditors argued that all small creditors should be eligible to make balloon-payment qualified mortgages if the loan is held in portfolio.

Fifth, and last, the Bureau solicited comment on the following issue. Section 1026.43(e)(5) could provide different legal status to loans with identical terms based solely on the creditor's size and intention to hold the loan in portfolio. The Bureau stated its belief that the size of and relationship lending model employed by small creditors provide significant assurances that the mortgage credit they extend will be responsible and affordable. However, to the extent that consumers may have a choice of creditors, some of whom are not small, it was not clear that consumers shopping for mortgage loans would be aware that their choice of creditor could significantly affect their legal rights. The Bureau solicited comment on the extent and significance of this risk generally. Specifically, the Bureau solicited comment on whether consumers who obtain small creditor portfolio loans likely could have obtained credit from other sources and on the extent to which a consumer who obtains a portfolio loan from a small creditor would be disadvantaged by the inability to make an affirmative claim of noncompliance with the ability-to-repay rules or to assert noncompliance in a foreclosure action.

Most commenters, including national and State trade groups representing banks and credit unions, as well as many individual small creditors, stated that small creditors make portfolio loans almost exclusively to consumers who do not qualify for secondary market financing for reasons unrelated to ability to repay, including: comparable sales that are not sufficiently similar, too distant, or too old; irregular zoning, lack of zoning, or problems with land records; condominiums that do not comply with secondary market owner-occupancy requirements; loan-to-value ratio; self-employed and seasonally-employed consumers who cannot prove continuance to the satisfaction of the secondary market; consumers with a new job; and small dollar loans that fall below secondary market thresholds. These commenters noted that these issues may be particularly problematic in rural areas but that they are common in suburban and urban areas as well. These commenters stated that consumers who qualify for secondary market financing generally obtain secondary market loans that are not held in portfolio and would be unaffected by proposed § 1026.43(e)(5).

Two commenters, a national trade group representing very large creditors and a very large creditor, argued that consumers would be disadvantaged by proposed § 1026.43(e)(5) because the rule would apply even in geographic areas where there are other creditors and because consumers comparing loans from different creditors would have to compare different legal rights that are difficult to value.

The Final Rule

Section 1026.43(e)(5) and the related comments are adopted as proposed. For the reasons stated below, the Bureau believes that § 1026.43(e)(5) is necessary and appropriate to preserve access to responsible, affordable credit for some consumers, including consumers who do not qualify for conforming mortgage credit.

Access to affordable, responsible credit. The Bureau continues to believe that § 1026.43(e)(5) is necessary to preserve access to credit for some consumers, including consumers who do not qualify for conforming mortgage credit, and will ensure that this credit is provided in a responsible, affordable way.

As discussed above in part II.A and in the section-by-section analysis of § 1026.43(b)(4), the Bureau understands that small creditors are a significant source of nonconforming mortgage credit. The Bureau believes that many of these loans would not be made by larger creditors because the consumers or properties involved are not accurately assessed by the standardized underwriting criteria used by larger creditors or because larger creditors are unwilling to make loans that cannot be sold to the securitization markets. The Bureau therefore believes that access to mortgage credit for some consumers would be restricted if small creditors stopped making nonconforming loans or significantly reduced the number of nonconforming loans they make.

Such an impact could be particularly significant in rural areas, where small creditors are a significant source of credit. As discussed above in part II.A, small creditors are significantly more likely than larger creditors to operate offices in rural areas, and there are hundreds of counties nationwide where the only creditors are small creditors and hundreds more where larger creditors have only a limited presence.

The Bureau also continues to believe that small creditors are particularly well suited to originate responsible, affordable mortgage credit. As discussed above in part II.A, the small creditors often are better able to assess ability to repay because they are more likely to base underwriting decisions on local knowledge and qualitative data and less likely to rely on standardized underwriting criteria. Because many small creditors use a lending model based on maintaining ongoing relationships with their customers, they often have a more comprehensive understanding of their customer's financial circumstances. Small creditors' lending activities often are limited to a single community, allowing the creditor to have an in-depth understanding of the economic and other circumstances of that community. In addition, because small creditors often consider a smaller volume of applications for mortgage credit, small creditors may be more willing and able to consider the unique facts and circumstances attendant to each consumer and property, and senior personnel are more likely to be able to bring their judgment to bear regarding individual underwriting decisions.

[158] One commenter, a consumer advocacy organization, urged the Bureau to adopt a lower debt-to-income ratio limit, such as 41 percent, for low-income borrowers for all qualified mortgages. In contrast, other commenters urged the Bureau to raise or eliminate the debt-to-income ratio limit for all qualified mortgages secured by property in Puerto Rico and Hawaii. These commenters argued that the 43 percent debt-to-income ratio limit would limit access to mortgage credit in Puerto Rico and Hawaii because debt-to-income ratios in these areas often are more than 43 percent. The Bureau did not propose and did not solicit comment regarding changes to the debt-to-income ratio limit for other categories of qualified mortgages and is not reconsidering this issue at this time.

Small creditors also have particularly strong incentives to make careful assessments of a consumer's ability to repay because small creditors bear the risk of default associated with loans held in portfolio and because each loan represents a proportionally greater risk to a small creditor than to a larger one. In addition, small creditors operating in limited geographical areas may face significant risk of harm to their reputations within their communities if they make loans that consumers cannot repay.

As many commenters reiterated, small creditors have repeatedly asserted that they will not lend outside the qualified mortgage safe harbor. The Bureau does not believe that small creditors face significant litigation risk from the ability-to-repay requirements. For the reasons stated above, the Bureau believes that small creditors as a group generally are better positioned to assess ability to repay than larger creditors, have particularly strong incentives to accurately assess ability to repay independent of the threat of ability-to-repay litigation, and historically have been very successful at accurately assessing ability to repay, as demonstrated by their comparatively low credit losses. In addition, the Bureau believes that because many small creditors use a lending model based on maintaining ongoing relationships with their customers, those customers may be more likely to pursue alternatives to litigation in the event that difficulties with a loan arise. The Bureau therefore believes that it is unlikely that small creditors will face significant liability for claims of noncompliance filed by their customers or will be significantly disadvantaged by recoupment and setoff claims in foreclosure actions.

However, the Bureau acknowledges that due to their size small creditors may find even a remote prospect of litigation risk to be so daunting that they may change their business models to avoid it. The Bureau also believes that the exit of small creditors from the residential mortgage market could create substantial short-term access to credit issues.

The Bureau therefore believes that, absent an amendment to the ability-to-repay and qualified mortgage rules, many small creditors will reduce or cease their mortgage lending activities, which would cause many consumers to face constraints on their access to credit that are entirely unrelated to their ability to repay. The Bureau believes that § 1026.43(e)(5) will preserve consumers' access to credit and, because of the characteristics of small creditors and portfolio lending described above, the credit provided generally will be responsible and affordable.

The Bureau is sensitive to concerns about the consistency of protections for all consumers and about maintaining a level playing field for market participants, but nevertheless believes that a differentiated approach is justified here. The commenters that suggested that consumers' interests are best served by subjecting all creditors to the same standards provided nothing that refutes the points raised in the Bureau's proposal regarding the low credit losses and unique business models of small creditors, their concerns about litigation risk and compliance burden, and the potential access to credit problems the Bureau believes will arise if the rule is not amended. The Bureau also disagrees that § 1026.43(e)(5) would not benefit consumers because it is limited to a small number of loans per creditor. Because there are thousands of small creditors as defined by § 1026.43(e)(5) in the United States, the Bureau believes that § 1026.43(e)(5) is likely to preserve access to affordable, responsible mortgage credit for hundreds of thousands of consumers annually.

Asset and originations limits. Section 1026.43(e)(5) includes portfolio loans made by creditors that have assets of $2 billion or less (adjusted annually for inflation) and, together with all affiliates, originate 500 or fewer first-lien mortgages each year. The Bureau proposed these thresholds to maintain consistency with the § 1026.43(f) qualified mortgage definition, which includes certain balloon loans made and held in portfolio by small creditors operating predominantly in rural or underserved areas, and with thresholds used in § 1026.35 as adopted by the Bureau's 2013 Escrows Final Rule. In the proposal, the Bureau emphasized the importance of maintaining consistent criteria, particularly between § 1026.43(e)(5) and (f), to avoid creating undesirable regulatory incentives (such as an incentive to make balloon loans where a creditor has the capability of making other mortgages that better protect consumers' interests) and to minimize compliance burdens by minimizing the number of metrics creditors must track to determine their eligibility for various regulatory provisions. The Bureau continues to believe that it is important to maintain consistency between these provisions.

Many commenters urged the Bureau to raise the limit above 500 first-lien originations for § 1026.43(e)(5), for instance by changing the types of loans counted or the numeric threshold. A national trade group representing small creditors and several other commenters argued that the originations limit in § 1026.43(e)(5) should be based on portfolio loans originated annually rather than all first-lien originations. These commenters argued that including loans sold to the secondary market in the origination threshold was not appropriate because the purpose of § 1026.43(e)(5) is to encourage portfolio lending and thereby preserve consumers' access to nonconforming credit.

On its face, the rationale advanced by these commenters argues against any limitation on the number of portfolio loans, as any limit would discourage portfolio lending in excess of that limit and all portfolio loans appear to carry with them a greater inherent incentive to exercise care in determining ability to repay than loans sold to the secondary market. However, one of the lessons learned in the recent financial crisis is that in the heat of a housing bubble, even portfolio lending standards can become too lax and standards that ensure responsible, affordable lending may be threatened.

Thus, the Bureau did not propose to provide qualified mortgage treatment to all portfolio loans, but rather only to portfolio loans made by small creditors on the theory that both the characteristics of the creditor—its small size, community-based focus, and commitment to relationship lending—and the inherent incentives associated with portfolio lending *together* would justify extending qualified mortgage status to a loan that would not meet the ordinary qualified mortgage criteria. Given this rationale, the Bureau does not believe it is appropriate to adopt an originations limit under which a creditor would be treated as a small, relationship-based creditor no matter how many loans it is selling to the secondary market.

Using publicly available HMDA data and call report data, the Bureau estimated the impact of adopting a limit based on portfolio loan originations instead of total first-lien originations. This change would add nearly one thousand creditors to the scope of § 1026.43(e)(5). These creditors appear to hold a significantly smaller percentage of the loans they originate in portfolio than creditors that would fall within § 1026.43(e)(5) as proposed, raising questions about the extent to which these creditors can be considered relationship lenders. This reinforces the point that the relationship lending model underlying the Bureau's rationale for § 1026.43(e)(5) cannot be defined by reference only to a subset of a creditor's

originations, but rather based on the nature of its overall operations. The Bureau therefore continues to believe that an originations limit based on total first-lien originations is the most appropriate way to ensure that the new category of qualified mortgages is appropriately cabined.

In addition, many commenters recommended increasing the originations limit from 500 first-lien mortgages to between 2,000 and 5,000. The principal rationale offered by these commenters is that banks with assets over $500 million often originate more than 500 first-lien mortgages per year and that the limitation on originations is not consistent with (*i.e.,* is significantly more restrictive than) the $2 billion asset limit.

The Bureau intended and believes that both elements of the threshold play independent and important roles. The Bureau believes that an originations limit is the most accurate means of limiting § 1026.43(e)(5) to the class of small creditors the business model of which the Bureau believes will best assure that the qualified mortgage definition facilitates access only to responsible, affordable credit. However, the Bureau believes that an asset limit is nonetheless important to preclude a very large creditor with relatively modest mortgage operations from taking advantage of a provision designed for much smaller creditors with much different characteristics and incentives. Due to general scale, such a creditor would not have the same type of community focus and reputational and balance-sheet incentives to assess ability to repay with sufficient care as smaller, community-based creditors, and is generally better able from a systems perspective to handle compliance functions.

Based on estimates from publicly available HMDA and call report data, the Bureau understands that, under the proposed criteria, the likelihood of falling within the scope of § 1026.43(e)(5) decreases as a creditor's size increases. The proposed limits include approximately 95 percent of creditors with less than $500 million in assets, approximately 74 percent of creditors with assets between $500 million and $1 billion, and approximately 50 percent of creditors with assets between $1 billion and $2 billion. These percentages are entirely consistent with the Bureau's rationale for § 1026.43(e)(5), as described above. As the size of an institution increases, it is to be expected that the scale of its lending business will increase as well. As the scale of a creditor's lending business increases, the likelihood that the institution is engaged in relationship-based lending and employing qualitative or local knowledge in its underwriting decreases. The Bureau therefore continues to believe that the proposed limit of 500 total first-lien originations is consistent with the rationale underlying § 1026.43(e)(5) and appropriate to ensure that consumers have access only to responsible, affordable mortgage credit.

Finally, some commenters argued that the Bureau should increase the asset limit from $2 billion to $5 billion or $10 billion. The Bureau does not believe this change is necessary to preserve access to credit. The traditional definition of a community bank has long been regarded as an institution with less than $1 billion in assets.[159] The Bureau's estimates show that § 1026.43(e)(5) as proposed includes over 90 percent of institutions with assets less than $1 billion. In its recent Community Bank Study, the FDIC employed a more complex definition that excluded a small number of institutions with assets under $1 billion based primarily on the nature of their assets and added a modest number of banks with assets greater than $1 billion based on a multi-factor test including criteria such as the geographic scope of the institution's operations and focus on core banking activities.[160] The Bureau has concluded that the FDIC's definition is too complex for regulatory purposes and no commenters advocated that the Bureau adopt it. However, the Bureau notes that the larger banks added by the FDIC's more nuanced definition of community bank had average assets of $1.9 billion.

In addition, the Bureau notes that a creditor with assets between $1 billion and $2 billion has, on average, 16 branches, 252 employees, and operations in 5 counties. In contrast, a creditor with between $2 billion and $10 billion in assets has, on average, 34 branches, 532 employees, and operations in 12 counties. As the staff and geographic scope of an institution increases, it becomes less and less likely that a creditor will engage in relationship lending or use qualitative or local knowledge in its underwriting. In addition, as an institution adds staff and branches, it is more likely from a systems perspective to handle compliance functions. The Bureau therefore believes that the proposed $2 billion asset limit is consistent with the rationale underlying § 1026.43(e)(5) and appropriate to ensure that consumers have access only to affordable, responsible credit.

Portfolio requirements. The Bureau continues to believe that the discipline imposed when small creditors make loans that they will hold in their portfolio is important to protect consumers' interests and to prevent evasion. The Bureau proposed that qualified mortgages under § 1026.43(e)(5) must be held in portfolio for three years to retain their status as qualified mortgages, thus matching the statute of limitations for affirmative claims for violations of the ability-to-repay rules. If a small creditor holds a qualified mortgage in portfolio for three years, it retains all of the litigation risk for potential violations of the ability-to-repay rules except in the event of a subsequent foreclosure.

The Bureau is extending qualified mortgage status only to portfolio loans made by small creditors, rather than all portfolio loans, because, as discussed above, the Bureau believes that small creditors are a unique and important source of non-conforming mortgage credit and mortgage credit in rural areas for which there is no readily available replacement, that small creditors are likely to be particularly burdened by the litigation risk associated with the ability-to-repay requirements and are particularly likely to reduce or cease mortgage lending if subjected to these rules without accommodation, and that small creditors have both strong incentives and particular ability to make these loans in a way that ensures that consumers are able to repay that may not be present for larger creditors.

As the Bureau acknowledged in the proposal, limitations on the ability of a creditor to sell loans in its portfolio may limit the creditor's ability to manage its regulatory capital levels by adjusting the value of its assets, may affect the creditor's ability to manage interest rate risk by preventing sales of seasoned loans, and may present other safety and soundness concerns. The Bureau has consulted with prudential regulators on these issues and continues to believe the proposed exceptions address these concerns without sacrificing the consumer protection provided by the portfolio requirement.

One commenter, a consumer advocacy organization, argued that the Bureau should not adopt the proposed exception that would allow a qualified mortgage under § 1026.43(e)(5) to retain its qualified mortgage status if it is transferred less than three years after origination because of a bank failure. The commenter argued that the need for supervisory action strongly suggests that

[159] *See, e.g., FDIC Community Banking Study,* p. 1–1.

[160] *FDIC Community Banking Study,* p. 1–1—1–5.

loans should not be entitled to the presumption of compliance associated with qualified mortgage status. The commenter further asserted that agencies charged with resolving failed creditors have sufficient authority to protect transferees from consumers' claims. The Bureau understands that creditors fail for many different reasons, many of which are entirely unrelated to underwriting practices for residential mortgage loans. The Bureau also continues to believe that this exception is necessary to ensure that resolutions are not impeded. The Bureau therefore declines to adopt the commenter's suggestion.

Underwriting requirements and debt-to-income ratio. Qualified mortgages under § 1026.43(e)(5) differ from qualified mortgages under the § 1026.43(e)(2) general definition in two key respects. First, as discussed above in the section-by-section analysis of § 1026.43(b)(4), qualified mortgages under § 1026.43(e)(5) are subject to a higher annual percentage rate threshold for the qualified mortgage safe harbor. Second, creditors are required to consider the consumer's debt-to-income ratio or residual income and to verify the underlying information generally in accordance with § 1026.43(c), but are not required to calculate the consumer's debt-to-income ratio according to appendix Q and there is no numeric limit on the consumers' debt-to-income ratio.

The Bureau continues to believe that consideration of debt-to-income ratio or residual income is fundamental to any determination of ability to repay. A consumer is able to repay a loan if he or she has sufficient funds to pay his or her other obligations and expenses and still make the payments required by the terms of the loan. Arithmetically comparing the funds to which a consumer has recourse with the amount of those funds the consumer has already committed to spend or is committing to spend in the future is necessary to determine whether sufficient funds exist.

However, for the same reasons that the Bureau declined to impose a specific 43-percent threshold for balloon-payment qualified mortgages under the balloon loan provision in § 1026.43(f), the Bureau does not believe it is necessary to impose a specific debt-to-income ratio or residual income threshold for this category of qualified mortgages. As discussed above, the Bureau believes that small creditors often are particularly able to make highly individualized determinations of ability to repay that take into consideration the unique characteristics and financial circumstances of a particular consumer. While the Bureau believes that many creditors can make mortgage loans with consumer debt-to-income ratios above 43 percent that consumers are able to repay, the Bureau also believes that portfolio loans made by small creditors are particularly likely to be made responsibly and to be affordable for the consumer even if such loans exceed the 43-percent threshold. The Bureau therefore believes that it is appropriate to presume compliance even above the 43-percent threshold for small creditors who meet the criteria set forth in § 1026.43(e)(5). The Bureau believes that the discipline imposed when small creditors make loans that they will hold in their portfolio is sufficient to protect consumers' interests in this regard. Because the Bureau is not adopting a specific limit on consumers' debt-to-income ratio, the Bureau does not believe it is necessary to require creditors to calculate debt-to-income ratio in accordance with a particular standard such as that set forth in appendix Q.

The Bureau does not believe it is appropriate to permit all small creditors to make balloon-payment qualified mortgages under § 1026.43(e)(5) as suggested by some commenters. The Bureau believes that Congress clearly indicated in the Dodd-Frank Act that only small creditors operating predominantly in rural or underserved areas should be eligible to originate balloon-payment qualified mortgages. However, as discussed below in the section-by-section analyses of § 1026.43(e)(6) and (f), the Bureau is providing a two-year transition period during which all small creditors may originate balloon-payment qualified mortgages. This transition period will allow the Bureau to study the existing definitions of rural and underserved to determine whether they adequately preserve consumers' access to responsible, affordable mortgage credit and will facilitate creditors' transition to alternatives to balloon-payment mortgages, such as adjustable-rate mortgages.

Valuation of legal rights by consumers. Finally, the Bureau is convinced that small creditor portfolio loans covered by § 1026.43(e)(5) are unlikely to be provided to consumers who qualify for secondary market financing or who can otherwise obtain mortgage credit. The Bureau therefore concludes that the risk that comparison shopping consumers will be unable to assess the value of the right to sue in the event of default or foreclosure is unlikely to be significant in practice. Also, as discussed above, the Bureau believes that small creditors' historically low credit losses demonstrate that the size and other characteristics of and relationship lending model employed by small creditors provide significant assurances that the mortgage credit they extend will be responsible and affordable. Because consumers are unlikely to receive loans from small creditors that result in default or foreclosure, it appears unlikely that consumers will be significantly disadvantaged by the inability to make an affirmative claim of noncompliance with the ability-to-repay rules or to assert noncompliance in a foreclosure action. The Bureau therefore believes that this issue is not sufficient to outweigh the significant benefit of § 1026.43(e)(5) in preserving access to credit.

Legal authority. Accordingly, the Bureau is exercising its authority under TILA sections 105(a), 129C(b)(2)(vi), and 129C(b)(3)(B)(i) to adopt § 1026.43(e)(5) as proposed for the reasons summarized below and discussed in more detail above. Under TILA section 105(a) the Bureau generally may prescribe regulations that provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary and proper to effectuate the purposes of TILA, which include the purposes of TILA 129C, and facilitate compliance with these purposes, among other things. The Bureau believes that these amendments are necessary and proper to ensure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans. This provision is consistent with the findings of TILA section 129C by ensuring that consumers are able to obtain responsible affordable credit, which informs the Bureau's understanding of its purposes.

Furthermore, the Bureau revises the qualified mortgage criteria in the statute to adopt this new definition by finding that this provision is necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C, necessary and appropriate to effectuate the purposes of TILA section 129C and to facilitate compliance with TILA section129C. As described above, the Bureau believes that, unless § 1026.43(e)(5) is adopted, small creditors will be less likely to make residential mortgage loans. Because small creditors are a significant source of nonconforming mortgage credit nationally and mortgage credit generally in rural or underserved areas, this would significantly limit access to

mortgage credit for some consumers. The Bureau also believes that the relationship lending model, qualitative local knowledge, and size of small creditors, combined with the intrinsic incentives of portfolio lending, provide strong assurances that these creditors typically will make reasonable and good faith determinations of consumers' ability to repay when originating loans pursuant to § 1026.43(e)(5). This provision is also necessary and proper to facilitate compliance with the purposes of TILA by easing the ability of small creditors to make qualified mortgages. The Bureau also believes that the provisions of § 1026.43(e)(5) relating to debt-to-income ratio or residual income are authorized by TILA section 129C(b)(2)(vi), which authorizes, but does not require, the Bureau to adopt guidelines or regulations relating to debt-to-income ratio or alternative measures of ability to pay regular expenses after payment of total monthly debt.

43(e)(6) Qualified Mortgage Defined—Temporary Balloon-Payment Qualified Mortgage Rules Background

As discussed above, TILA section 129C(b) and the Bureau's rules thereunder, § 1026.43(e), provide that a creditor or assignee may presume that a loan has met the ability-to-repay requirements described in TILA section 129C(a)(1) through (4) and the Bureau's rules thereunder, § 1026.43(c), if a loan is a qualified mortgage. TILA section 129C(b)(2)(A)(ii) provides that qualified mortgages generally cannot include a balloon payment. Accordingly, § 1026.43(e)(2) of the Bureau's rules provides a general qualified mortgage definition that excludes loans with a balloon payment. In addition, § 1026.43(e)(4) provides a temporary qualified mortgage definition that also excludes balloon-payment loans.

However, TILA section 129C(b)(2)(E) permits the Bureau to provide by regulation an alternate qualified mortgage definition that includes certain balloon payment mortgages originated and held in portfolio by small creditors operating predominantly in rural or underserved areas. The Bureau exercised this authority in adopting § 1026.43(f). Section 1026.43(f) allows creditors with less than $2 billion in assets that originate, together with all affiliates, fewer than 500 first-lien mortgages annually to originate balloon-payment qualified mortgages if the creditor operates predominantly in rural or underserved areas and if certain other requirements are met. The Bureau adopted definitions of rural and underserved in § 1026.35(b)(2)(iv).

As discussed above in the section-by-section analysis of § 1026.43(e)(5), the Bureau proposed and is adopting a fourth category of qualified mortgage which includes loans originated and held in portfolio by small creditors that meet the same asset and originations criteria regardless of whether they operate predominantly in rural and underserved areas. Qualified mortgages in this category are subject to different, more relaxed requirements regarding debt-to-income ratio and are covered by the regulatory safe harbor at a higher annual percentage rate than other qualified mortgages. However, because TILA section 129C(b)(2)(A)(ii) specifies that qualified mortgages generally may not have a balloon payment, § 1026.43(e)(5) does not include mortgages with a balloon payment.

The Bureau's Proposal and Comments Received

Prohibition on balloon payments generally. As discussed above, in proposing the new category of qualified mortgage for certain small creditor portfolio loans under § 1026.43(e)(5), the Bureau solicited comment regarding the loan feature and underwriting requirements with which qualified mortgages under proposed § 1026.43(e)(5) would have to comply. Specifically, the Bureau solicited comment on whether qualified mortgages under proposed § 1026.43(e)(5) should be exempt from provisions of § 1026.43(e)(2) in addition to those related to debt-to-income ratio or should be subject to any other loan feature or underwriting requirements, either in lieu of or in addition to those proposed.

A large number of commenters, including national and State trade groups representing creditors and many individual small creditors, argued that § 1026.43(e)(5) would not have the intended effect of preserving access to nonconforming mortgage credit and mortgage credit in rural areas unless § 1026.43(e)(5) permitted small creditors to make balloon-payment mortgages within the qualified mortgage safe harbor regardless of whether they operate predominantly in rural or underserved areas.

These commenters argued that small creditors rely on balloon-payment provisions to manage interest rate risk for the overwhelming majority of their residential mortgage portfolio loans. One national trade group representing small creditors estimated that 75 percent of all residential mortgages in small creditors' portfolios have a balloon-payment feature. Many small creditors who reported information regarding their own portfolios reported that between 90 and 100 percent of their portfolio mortgage loans include a balloon-payment feature.

These commenters also stated that small creditors that rely on balloon-payment features generally do not have the capability at this time to originate and service adjustable-rate mortgages, also known as ARMs. Adjustable-rate mortgages would serve as an alternate way to manage interest rate risk and are permissible under § 1026.43(e)(5) as proposed and finalized. However, commenters expressed concerns that adjustable-rate mortgages are more difficult for small creditors to originate and service because of the systems and disclosures required.

Finally, these commenters reiterated that small creditors generally will be unwilling or unable to lend outside the qualified mortgage safe harbor because of the associated litigation risk. As such, argued these commenters, the prohibition on balloon-payments under § 1026.43(e)(5) would cause a significant reduction in consumers' access to nonconforming credit.

These commenters also asserted that small creditors have been originating balloon-payment loans for many years without significant harm to consumers and that balloon-payment loans made by small creditors generally have very low default rates that are a fraction of average default rates for mortgage loans generally. These commenters added that portfolio mortgage loans are a significant portion of assets and a significant revenue stream for most small creditors. Therefore, the commenters argued, the inability to make balloon-payment loans within the qualified mortgage safe harbor will cause serious financial harm to many small creditors, further reducing consumers' access to nonconforming and other mortgage credit.

Rollover balloons. The Bureau also solicited comment regarding consumers with balloon-payment loans originated before the January 10, 2014, effective date of the 2013 ATR Final Rule for which the balloon payment will become due after the effective date. The Bureau noted that small creditors that use balloon-payment loans to manage interest rate risk generally refinance the remaining principal when the balloon payment becomes due. In other words, the small creditors who follow this practice generally use the balloon payment feature as an opportunity to adjust the loan's interest rate, not because they expect the consumer will repay the loan in full before the balloon payment becomes due.

In the proposal, the Bureau stated its belief that the balloon-payment qualified mortgage provision in § 1026.43(f) and the small creditor portfolio exemption in proposed § 1026.43(e)(5) would be adequate to facilitate refinancing of balloon-payment loans for which the balloon-payment becomes due after January 10, 2014. However, the Bureau solicited feedback regarding whether these provisions were adequate for this purpose or whether creditors would need additional time beyond the January 10, 2014, effective date or would require any additional accommodations, modifications, or exemptions.

Several commenters, including small creditors and creditor trade groups, specifically acknowledged the difficulties presented by balloon-payment loans originated before the effective date. These commenters stated the balloon-payment mortgages offered by small creditors generally have payments (other than the balloon) that amortize the loan over 30 years. These commenters stated that consumers most often take these loans not because they expect to repay the loan before the balloon payment becomes due but based on creditors' assurances that they will be able to refinance the loan, albeit at a different rate. In other words, these commenters confirmed that small creditors use balloons in a way that is functionally similar to a long-term adjustable-rate mortgage. These commenters asserted that small creditors generally are committed to refinancing these loans for their customers. They stated, however, that they will be unable or unwilling to do so after the effective date unless changes are made to permit them to originate new balloon-payment loans within the qualified mortgage safe harbor.

These commenters stated that, if the small creditors who originated these loans are unable or unwilling to refinance them, consumers will be forced to seek refinancing elsewhere. According to these commenters, consumers with balloon-payment loans from small creditors generally do not qualify for secondary market financing, and many of these consumers therefore will have difficulty finding other refinancing or restructuring options. The commenters asserted that in extreme circumstances some consumers who are unable to refinance or make the balloon payment might face foreclosure if they were unable to secure refinancing.

Commenters who raised this issue generally argued that the Bureau should exempt loans that refinance a balloon-payment loan originated before the effective date from the ability-to-repay and qualified mortgage rules or significantly broaden the ability of creditors to make balloon loans within the qualified mortgage safe harbor such that a greater portion of these refinancing loans would be covered.

The Final Rule

The Bureau is adopting new § 1026.43(e)(6), which provides a two-year transition period during which small creditors as defined by § 1026.43(e)(5) can originate balloon-payment qualified mortgages even if they do not operate predominantly in rural or underserved areas. The Bureau is adopting new § 1026.43(e)(6) because it believes that doing so is necessary to preserve access to responsible, affordable mortgage credit for some consumers. As discussed further below and in connection with § 1026.43(f), during the two-year period in which § 1026.43(e)(6) is in place, the Bureau intends to review whether the definitions of ''rural'' or ''underserved'' should be further adjusted for purposes of the qualified mortgage rule and to explore how it can best facilitate the transition of small creditors' who do not operate predominantly in rural or underserved areas from balloon-payment loans to adjustable-rate mortgages as Congress intended under the Dodd-Frank Act. At the end of the period, however, the Bureau expects that the statutory framework will take full effect such that balloon-payment loans are treated as qualified mortgages only where originated by small creditors operating predominantly in rural or underserved areas under § 1026.43(f).

New § 1026.43(e)(6) defines an additional category of qualified mortgages that, like § 1026.43(e)(5), includes loans originated and held in portfolio by creditors that:

- Have total assets that do not exceed $2 billion as of the end of the preceding calendar year (adjusted annually for inflation); and
- Together with all affiliates, extended 500 or fewer first-lien covered transactions during the preceding calendar year.

New § 1026.43(e)(6) is not limited to small creditors operating predominantly in rural or underserved areas. However, the new provision incorporates by reference all other requirements under the § 1026.43(f) balloon-payment qualified mortgage definition. The loan therefore cannot have:

- Payments that result in an increase of the principal balance;
- A term longer than 30 years; and
- Points and fees greater than 3 percent of the total loan amount (or, for smaller loans, a specified amount).

The creditor must consider and verify the consumer's current or reasonably expected income or assets (other than the dwelling and attached real property that secure the loan) and the consumer's current debt obligations, alimony, and child support. The creditor also must consider the consumer's monthly debt-to-income ratio or residual income. As with § 1026.43(e)(5) and (f), there is no numeric limit on a consumer's debt-to-income ratio and creditors are not required to calculate debt-to-income ratio according to appendix Q. In addition, the loan must provide for scheduled payments that are substantially equal and calculated using an amortization period that does not exceed 30 years, an interest rate that does not increase over the term of the loan, and a term of 5 years or longer.

A loan must not be subject at consummation to a commitment to be acquired by any person other than a person that also meets the above asset-size and number of transactions criteria. A loan loses its qualified mortgage status under § 1026.43(e)(6) if it is sold, assigned, or otherwise transferred, subject to exceptions for transfers that are made three or more years after consummation, to another qualifying institution, as required by a supervisory action, or pursuant to a merger or acquisition.

As with all qualified mortgages, a qualified mortgage under § 1026.43(e)(6) receives either a rebuttable or conclusive presumption of compliance with the ability-to repay requirements in § 1026.43(c), depending on the annual percentage rate. However, as described above in the section-by-section analysis of § 1026.43(b)(4), the Bureau is adopting an alternate definition of higher-priced covered transaction for first-lien covered transactions that are qualified mortgages under § 1026.43(e)(5) and (f). As also is discussed above in the section-by-section analysis of § 1026.43(b)(4), this alternate definition applies to qualified mortgages under § 1026.43(e)(6) as well. As such, § 1026.43(b)(4) provides that a first-lien covered transaction that is a qualified mortgage under proposed § 1026.43(e)(6) is a higher-priced covered transaction if the annual percentage rate exceeds APOR for a comparable transaction by 3.5 or more percentage points. This extends the qualified mortgage safe harbor described in § 1026.43(e)(1)(i) to first-lien qualified mortgages defined under proposed § 1026.43(e)(6) even if those loans have annual percentage rates

between 1.5 and 3.5 percentage points higher than APOR. Such loans otherwise would be covered by the rebuttable presumption of compliance described in § 1026.43(e)(1)(ii).

As discussed below, § 1026.43(e)(6) is intended to provide a temporary transition period during which small creditors that do not operate predominantly in rural and underserved areas can originate balloon-payment qualified mortgages. Section 1026.43(e)(6) therefore applies only to loans consummated on or before January 10, 2016, two years after the effective date of the 2013 ATR Final Rule. Qualified mortgages originated under § 1026.43(e)(6) on or before January 10, 2016, will retain their qualified mortgage status after January 10, 2016, as long as all other requirements, such as the requirement to retain the loan in portfolio subject to certain exceptions, are met.

The Bureau believes § 1026.43(e)(6) appropriately balances consumer protection and access to credit issues. As discussed above in the section-by-section analyses of § 1026.43(b)(4) and (e)(5), the Bureau believes that small creditors are an important source of mortgage credit, including nonconforming mortgage credit, and that there would be a significant reduction in consumers' access to credit if small creditors were to substantially reduce the number of residential mortgage loans they make or cease mortgage lending altogether. The Bureau also understands that small creditors generally do not originate long-term fixed-rate portfolio loans because of the associated interest rate risk, that many small creditors do not offer ARMs because they do not have the compliance and other systems in place to originate and service them, and that many small creditors have expressed reluctance to offer balloon-payment mortgages outside the qualified mortgage safe harbor because of the associated litigation risk. The Bureau also understands that some consumers may find it more inconvenient, more costly, or more difficult to refinance their existing balloon-payment loans if small creditors are unable or unwilling to refinance these loans because these consumers would have to seek financing from other creditors. The Bureau also is sensitive to concerns that some consumers may be unable to find alternative financing and therefore could face foreclosure.

Commenters' preferred solution is for the Bureau to significantly and permanently broaden the ability of all small creditors to make balloon-payment mortgages that are either exempt from the ability-to-repay rules or within the qualified mortgage safe harbor. As discussed further below with regard to § 1026.43(f), the Bureau believes it is appropriate to use the two-year transition period to consider whether it can develop more accurate or precise definitions of rural and underserved. However, the Bureau believes that Congress made a deliberate policy choice in the Dodd-Frank Act not to extend qualified mortgage status to balloon-payment products outside of such areas. The Bureau believes that with appropriate transition time, and perhaps implementation support, small creditors can develop adjustable-rate mortgage products that will enable them to manage interest rate risk in a manner that poses less risk for consumers. Accordingly, the Bureau also will focus during the two-year transition period on facilitating small creditors' conversion to adjustable-rate mortgage products.

The Bureau understands that adjustable-rate mortgages offered today by many creditors would fall within that qualified mortgage safe harbor and incorporate interest rate adjustment features similar to those of the balloon-payment mortgages used by many small creditors. For example, the interest rate of a 5/5 ARM adjusts five years after consummation and every five years thereafter for the duration of the loan term, paralleling the interest rate adjustment terms of an amortizing 5-year balloon-payment mortgage that is expected to be refinanced until it is paid off. The Bureau also understands that there are differences between adjustable-rate and balloon-payment mortgages that may be significant for some creditors. Interest rate adjustments for adjustable-rate mortgages are tied to changes in an index rate, and commonly used index rates (*e.g.,* the London Interbank Offered Rate or ''LIBOR'') may not track small creditors' cost of funds. Interest rates for adjustable-rate mortgages generally are capped at a certain amount above the initial rate, and this cap makes managing interest rate risk more complex. In addition, creditors that do not currently originate ARMs are likely to incur costs for developing the capability to do so (such as by purchasing additional modules for existing lending platforms), and there are additional expenses associated with servicing adjustable-rate mortgages, as consumers must be notified before each interest rate adjustment and servicing systems must be equipped to adjust the interest rate and payment amount.

However, adjustable-rate mortgages also pose significantly less risk to consumers. The Bureau believes that balloon-payment mortgages are particularly risky for consumers because the consumer must rely on the creditors' nonbinding assurances that the loan will be refinanced before the balloon payment becomes due. Even a creditor with the best of intentions may find itself unable to refinance a loan when a balloon payment becomes due. Changes in the consumer's credit profile may affect the creditor's willingness to refinance or the price of the loan, and consumers may be unable to anticipate the new rate that will be offered and suddenly find that they are unable to afford it. Consumers with balloon-payment mortgages therefore face the periodic possibility of losing their property even if they perform their obligations under the terms of the loan. Adjustable-rate mortgages present less risk to consumers because they do not require refinancing and because interest rate adjustments are calibrated over the life of the loan and therefore are more predictable.

Publicly available data from reports filed with the National Credit Union Administration indicate that around 20 percent of small credit unions, including some with assets below $150 million, originate adjustable-rate mortgages and only 18 percent of small credit unions originate balloon-payment mortgages but not adjustable-rate mortgages. This suggests that small creditors can manage interest rate risk, lend safely and soundly, and afford the expense and compliance burden associated with originating adjustable-rate mortgages.

The Bureau believes that Congress made a clear policy choice in the Dodd-Frank Act that small creditors not operating predominantly in rural or underserved areas must ultimately conduct their residential mortgage business using adjustable-rate mortgages or other alternatives to balloon-payment mortgages. However, as discussed below in the section-by-section analysis of § 1026.43(f), the Bureau believes that further study of the existing definitions of rural and underserved is warranted. In addition, the Bureau acknowledges that many small creditors are not equipped to offer alternatives to balloon-payment mortgages today and are unlikely to be so equipped by the January 10, 2014, effective date. If small creditors are unable or unwilling to originate new loans as of that date, the Bureau believes there will be deleterious effects on access to nonconforming credit and possible harm to consumers with balloon-payment mortgages originated before the effective date that expect to refinance their loans with the same creditor when the balloon payment becomes due.

The Bureau therefore believes that, in order to preserve access to affordable, responsible credit, it is necessary and appropriate to provide small creditors, as defined in § 1026.43(e)(5), with a two-year transition period after the effective date during which they can continue to originate balloon loans. The Bureau believes that this two-year period will enable the Bureau to re-examine the definitions of rural or underserved to determine, among other things, whether these definitions accurately identify communities in which there are limitations on access to credit and whether it is possible to develop definitions that are more accurate or more precise. The Bureau may consider proposing changes to the definitions of rural or underserved based on the results of its inquiry. The two-year transition period also will facilitate small creditors' conversion to adjustable-rate mortgage products or other alternatives to balloon-payment loans.

Accordingly, the Bureau is exercising its authority under TILA sections 105(a), 129C(b)(2)(vi), and 129C(b)(3)(B)(i) to adopt § 1026.43(e)(6) for the reasons summarized below and discussed in more detail above. Under TILA section 105(a) the Bureau generally may prescribe regulations that provide for such adjustments and exceptions for all or any class of transactions that the Bureau judges are necessary and proper to effectuate the purposes of TILA, which include the purposes of TILA 129C, and facilitate compliance with these purposes, among other things. The Bureau believes that these amendments are necessary and proper to ensure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans. This provision is consistent with the findings of TILA section 129C by ensuring that consumers are able to obtain responsible affordable credit, which informs the Bureau's understanding of its purposes.

Furthermore, the Bureau revises the qualified mortgage criteria in the statute to adopt this new definition by finding that this provision is necessary and proper to ensure that responsible, affordable mortgage credit remains available to consumers in a manner consistent with the purposes of TILA section 129C, necessary and appropriate to effectuate the purposes of TILA section 129C and to facilitate compliance with TILA section129C. As described above, the Bureau believes that, unless § 1026.43(e)(6) is adopted, small creditors will be less likely to make residential mortgage loans. Because small creditors are a significant source of nonconforming mortgage credit nationally and mortgage credit generally in rural or underserved areas, this would significantly limit access to mortgage credit for some consumers. The Bureau also believes that the relationship lending model, qualitative local knowledge, and size of small creditors, combined with the intrinsic incentives of portfolio lending, provide strong assurances that these creditors typically will make reasonable and good faith determinations of consumers' ability to repay when originating loans pursuant to § 1026.43(e)(6). This provision is also necessary and proper to facilitate compliance with the purposes of TILA by easing the ability of small creditors to make qualified mortgages. The Bureau also believes that the provisions of § 1026.43(e)(6) relating to debt-to-income ratio or residual income are authorized by TILA section 129C(b)(2)(vi), which authorizes, but does not require, the Bureau to adopt guidelines or regulations relating to debt-to-income ratio or alternative measures of ability to pay regular expenses after payment of total monthly debt.

43(f) Balloon-Payment Qualified Mortgages Made by Certain Creditors

Section 1026.43(f) provides that certain balloon loans made and held in portfolio by certain small creditors operating predominantly in rural or underserved areas are qualified mortgages. The Bureau did not propose specific amendments to § 1026.43(f), but explained that if proposed § 1026.43(e)(5) were adopted with changes inconsistent with § 1026.43(f), the Bureau would consider and might adopt parallel amendments to § 1026.43(f) in order to keep these sections of the regulation consistent.

The Bureau solicited comment on the advantages and disadvantages of maintaining consistency between § 1026.43(e)(5) and (f). Commenters generally did not specifically discuss the importance of consistency, although most commenters advocating for changes to § 1026.43(e)(5) stated that conforming changes should be made to § 1026.43(f) as well. However, many commenters raised concerns regarding the scope of the Bureau's definitions of rural and underserved under § 1026.43(f). Commenters including national and State trade groups representing creditors and dozens of small creditors argued that the Bureau's definitions of rural and underserved are too restrictive and do not adequately preserve consumers' access to credit. Commenters were particularly critical of the Bureau's definition of ''rural,'' which they asserted excluded many communities that are considered rural under other legal or regulatory definitions or that are commonly viewed as rural because of their small, isolated, agricultural or undeveloped characteristics. Some of these commenters proposed that the Bureau adopt alternate definitions of ''rural,'' such as those used by the U.S. Department of Agriculture's Rural Housing Loan Program or the Farm Credit System. Others suggested that all creditors or all small creditors should be eligible to make balloon-payment qualified mortgages if the loan is held in portfolio, or that a balloon-payment mortgage should be considered a qualified mortgage if the consumer and property have certain characteristics that suggest the loan would not be eligible for sale to the secondary market.

Other commenters raised concerns about the requirement that balloon-payment qualified mortgages have a loan term of five years or longer. These commenters asserted that many small creditors currently originate balloon-payment loans with shorter terms and would be unable to manage interest rate risk using balloon-payment loans with a five-year term.

One commenter, a consumer advocacy organization, argued that all qualified mortgages should be long-term, fixed-rate loans and that the § 1026.43(f) definition of balloon-payment qualified mortgages should be abandoned.

As discussed above in the section by section analysis of § 1026.43(e)(5), § 1026.43(e)(5) as adopted is consistent with existing § 1026.43(f). The Bureau did not propose and did not solicit comment regarding amendments § 1026.43(f) except with respect to preserving consistency with § 1026.43(e)(5), and the Bureau is not reconsidering the definitions of rural and underserved and the § 1026.43(f) restrictions on the terms of balloon-payment qualified mortgages at this time. The Bureau is therefore not adopting any changes to § 1026.43(f) in this rulemaking.

However, the Bureau is sensitive to concerns expressed by commenters that the existing definitions of rural and underserved may not include some communities in which there are limitations on access to credit related to the community's rural character or the small number of creditors operating in the community. For example, the Bureau is aware that there are drawbacks to a county-based system for defining ''rural'' and ''undeserved,'' such as in western States where counties may cover extremely large

areas. As discussed above in the section-by-section analysis of § 1026.43(e)(6), the Bureau is providing a two-year transition period during which small creditors can originate balloon payment qualified mortgages even if they do not operate predominantly in rural or underserved areas. In addition to providing time for small creditors to further develop their capacity to offer adjustable-rate mortgages, the Bureau expects to re-examine the definitions of rural or underserved during this time to determine, among other things, whether these definitions accurately identify communities in which there are limitations on access to credit and whether it is possible to develop definitions that are more accurate or more precise. The Bureau may consider proposing changes to the definitions of rural or underserved based on the results of its inquiry.

43(g) Prepayment Penalties

The Bureau is adopting conforming amendments to § 1026.43(g) to include references to § 1026.43(e)(5) and (6), as described in the section-by-section analyses of those sections, above.

VI. Effective Date

This final rule is effective on January 10, 2014. The rule applies to transactions for which the creditor received an application on or after that date. The Bureau received several comments requesting various delays in the effective date. For example, one commenter asked the Bureau to delay the effective date for all of § 1026.43 by six months to provide sufficient time to implement the processes, procedures, and systems changes needed to comply with the ability-to-repay requirements. The Bureau has considered these comments, but declines to delay the effective date. The Bureau acknowledges the challenges identified by commenters, but believes that an effective date of January 10, 2014 provides sufficient time to implement the required changes. Also, as discussed in the 2013 ATR Final Rule, the Bureau believes that this effective date will ensure that consumers receive the protections in these rules as soon as reasonably practicable, taking into account the timeframes established in section 1400(c) of the Dodd-Frank Act, the overlapping provisions of the other title XIV final rules, the Bureau's efforts at facilitating regulatory implementation, and the need to afford creditors, other affected entities, and other industry participants sufficient time to implement the more complex or resource-intensive new requirements.[161]

VII. Dodd-Frank Act Section 1022(b)(2) Analysis

In developing the final rule, the Bureau has considered potential benefits, costs, and impacts.[162] In addition, the Bureau has consulted, or offered to consult with, the prudential regulators, SEC, HUD, FHFA, the Federal Trade Commission, and the Department of the Treasury, including regarding consistency with any prudential, market, or systemic objectives administered by such agencies. The Bureau also held discussions with or solicited feedback from the United States Department of Agriculture, Rural Housing Service, the Federal Housing Administration, and the Department of Veterans Affairs regarding the potential impacts of the final rule on those entities' loan programs.

The Bureau is issuing this final rule to adopt certain exemptions, modifications, and clarifications to TILA's ability-to-repay rule. On January 10, 2013, the Bureau issued the 2013 ATR Final Rule to implement the ability-to-repay requirements of the Dodd-Frank Act that generally require a creditor to make a reasonable, good faith determination of a consumer's ability to repay a mortgage loan and other statutory provisions. *See* 78 FR 6407 (Jan. 30, 2013). At the same time, the Bureau issued the 2013 ATR Proposed Rule related to certain proposed exemptions, modifications, and clarifications to the ability-to-repay rule. *See* 78 FR 6621 (Jan. 30, 2013).

The final rule provides exceptions to the 2013 ATR Final Rule, which implements the statute's inclusion of loan originator compensation in points and fees. Specifically, in the final rule, payments by consumers to mortgage brokers need not be counted as loan originator compensation where such payments already have been included in points and fees as part of the finance charge. In addition, compensation paid by a mortgage broker to its employee loan originator need not be included in points and fees, nor does compensation paid by a creditor to its own loan originator employees. However, consistent with the statute and 2013 ATR Final Rule, compensation paid by a creditor to a mortgage broker continues to be included in points and fees in addition to any origination charges paid by a consumer to the creditor.

The final rule also provides certain exemptions from the ATR requirements. These include exemptions for extensions of credit made by certain types of creditors, in accordance with applicable conditions, including creditors designated by the U.S. Department of the Treasury as Community Development Financial Institutions; creditors designated by the U.S. Department of Housing and Urban Development as either a Community Housing Development Organization or a Downpayment Assistance Provider of Secondary Financing; and certain creditors designated as nonprofit organizations under section 501(c)(3) of the Internal Revenue Code. The final rule also exempts from the ability-to-repay requirements extensions of credit made pursuant to a program administered by a housing finance agency (HFA) and extensions of credit made pursuant to an Emergency Economic Stabilization Act program.

The final rule creates two new definitions for loans that can be qualified mortgages. The final rule creates a new category of qualified mortgages that includes, among other conditions, certain loans originated and held on portfolio by creditors that have total assets of less than $2 billion at the end of the previous calendar year and, together with all affiliates, originated 500 or fewer first-lien covered mortgages during the previous calendar year. In addition, the final rule creates a two-year transition period during which balloon loans originated and held on portfolio by small creditors (as defined above) who do not operate predominantly in rural or underserved areas can be qualified mortgages under defined conditions. Such loans would not be eligible for qualified mortgage status under section 1026.43(f) because under the statute, that provision is limited to creditors that operate predominantly in rural or underserved areas. The final rule also allows small creditors to charge a higher annual percentage rate of 3.5 percentage points above the Average Prime Offer Rate for first-lien qualified mortgages, and still benefit from a conclusive presumption of compliance (or safe harbor). This higher threshold applies to the new small creditor portfolio qualified mortgages just described, to first-lien balloon-payment qualified mortgages originated by small creditors operating

[161] *See* 78 FR 6555 (Jan. 30, 2013).

[162] Specifically, section 1022(b)(2)(A) of the Dodd-Frank Act calls for the Bureau to consider the potential benefits and costs of a regulation to consumers and covered persons, including the potential reduction of access by consumers to consumer financial products or services; the impact on depository institutions and credit unions with $10 billion or less in total assets as described in section 1026 of the Dodd-Frank Act; and the impact on consumers in rural areas.

predominantly in rural or underserved areas and, to balloon mortgages originated by other small creditors during the two-year transition period.

This analysis generally examines the benefits, costs, and impacts of the final rule against the baseline of the January 2013 ATR Rule.[163] For the analyses considered here, the Bureau believes that the baseline of the 2013 ATR Final Rule is the most appropriate and informative. Because the final rule includes amendments and clarifications to the January 2013 ATR Rule, a comparison to the January baseline focuses precisely on the impacts of such provisions. The analyses in this section rely on data that the Bureau have obtained, the record including comments received in the proposed rule, and the record established by the Board and Bureau during the development of the 2013 ATR Final Rule. However, the Bureau notes that for some analyses, there are limited data available with which to quantify the potential costs, benefits, and impacts of the proposal. Still, general economic principles together with the limited data that are available provide insight into the benefits, costs, and impacts and in these cases, the analysis provides a qualitative discussion of the benefits, costs, and impacts of the final rule.

Commenters on the proposed rule did not submit comments specifically addressing the analyses under Section 1022 contained in the Supplemental Information accompanying the proposal. However, several did address the overall benefits, costs and impacts of the proposal.[164] The comments are discussed throughout the section-by-section analyses above.

A. Potential Benefits and Costs to Consumers and Covered Persons

1. Points and Fees Calculation

In the final rule, payments by consumers to mortgage brokers need not be counted as loan originator compensation where such payments already have been included in points and fees as part of the finance charge. In addition, compensation paid by a mortgage broker to its employee loan originator need not be included in points and fees, nor does compensation paid by a creditor to its own loan originator employees. However, compensation paid by a creditor to a mortgage broker is included in points and fees in addition to any origination charges paid by a consumer to the creditor.

As noted above, the Bureau believes that the most appropriate baseline against which to consider these changes is the 2013 ATR Final Rule. Consistent with the literal language of the statute, the 2013 ATR Final Rule provided that loan originator compensation be treated as additive to other elements of points and fees and that compensation is added as it flows downstream to the loan originator. As discussed in the section-by-section analyses above, the Bureau is now invoking its exception and revision authorities to alter the statutory additive approach to exclude certain compensation.

At a general level, the exclusion (inclusion) of additional sources of compensation in the points and fees calculation decreases (increases) the total amount of points and fees. As explained in the 2013 ATR Final Rule, keeping all other provisions of a given loan fixed, calculations that exclude additional amounts of compensation will result in a greater number of loans being eligible as qualified mortgages. Conversely, calculations that include additional amounts of compensation are less likely to achieve qualified mortgage status. For loans that are not eligible to be qualified mortgages, the costs of origination may be slightly higher as a result of the slightly increased liability for the lender and any assignees and of possibly increased compliance costs related to the origination and documentation of the loan. If these costs are passed along, consumers' costs for these loans may also increase. However, these consumers will also have the added consumer protections that accompany loans made under the general ability-to-repay provisions. In some instances, such up-front points and fees could be folded into the interest rate in order to maintain loans' status as qualified mortgages, which in turn could move loans out of the safe harbor and into the rebuttable presumption. The 2013 ATR Final Rule discussed the impacts of the ability-to-repay/qualified mortgage regime on consumers in depth including the nature of the liability regime. To the extent that the impact of various provisions of this rule on consumers is essentially to expand or contract coverage of the ability-to-repay/qualified mortgage regime, the general discussion of the impacts from the January 2013 rule is informative for each of the various provisions.

The exclusion (inclusion) of additional loan originator compensation amounts in points and fees may similarly lead fewer (more) loans to exceed the points and fees triggers and rate triggers for high-cost mortgages under HOEPA. Based on the history of high-cost mortgage loans, the Bureau believes that loans exceeding the high-cost thresholds are less likely to be offered unless they can be restructured with lower up front points and fees. Consumers who are offered and accept loans above the high-cost mortgage threshold will have the added consumer protections that accompany high-cost mortgage loans; other consumers may still able to take out their loan by paying a higher interest rate and less up-front.[165] The January 2013 HOEPA rule discussed the impacts of the high-cost mortgage regime on consumers in depth including the nature of the liability regime. To the extent that the impact of various provisions of this rule on consumers is essentially to expand or contract coverage of the high cost mortgage regime, the general discussion of the impacts from the January 2013 HOEPA rule is informative for each of the various provisions.

Measured against the 2013 ATR Final Rule baseline, the final rule excludes certain compensation from the points and fees calculation in both the wholesale and retail channels. In the wholesale channel, two types of compensation are excluded: Payments by consumers to mortgage brokers where such payments are already included in points and fees as part of the finance charge and compensation paid by a mortgage broker to its employee loan originator. In the retail channel, compensation paid by a creditor to its own loan originator employees is also excluded. Because of these exclusions, more loans will satisfy the points and fees threshold for qualified mortgages and fewer loans will exceed the points and fees threshold for high-cost mortgages. As described above, for covered persons, the costs of supplying such loans should be slightly reduced; consumers with such loans should therefore benefit from greater access to credit and lower costs, but would have a more restricted ability to challenge violations of the ability-to-repay rules and would not benefit from

[163] The Bureau has discretion in future rulemakings to choose the relevant provisions to discuss and to choose the most appropriate baseline for that particular rulemaking.

[164] In conducting the interagency consultation process under section 1022(b)(2)(B), the Bureau received communications for the public record regarding the proposed rule. The FDIC, HUD, and OCC wrote the Bureau regarding the proposed provisions on loan originator compensation and FHFA and HUD wrote the Bureau regarding the proposed exemptions from the ability-to-repay requirements. These comments are discussed in more detail in the section-by-section analyses above.

[165] The ability to cover up-front costs in the interest rate depends on the characteristics of the borrower and the loan. The interest rate threshold for high-cost mortgages under HOEPA could also potentially limit this option.

the protections afforded to high-cost mortgages.

The magnitude of both of these effects—changes in the status of loans as qualified mortgages or high cost mortgages and the extent to which lenders may adjust pricing and compensation practices in response to such provisions—will determine the costs, benefits, and impacts on covered persons and consumers. As noted earlier, comprehensive and representative data that include points and fees as well as loan originator compensation is not readily available. The Bureau did receive some data, however, in response to its requests included in the proposed rule. In a communication that has been made part of the record, one industry trade group submitted data to the Bureau that contained loan-level information for three anonymous retail lenders. These data included information on points and fees and estimates of loan originator compensation. Based on the limited data in this submission, excluding compensation paid by retail lenders to their loan officers has a minor impact on the number of loans below the qualified mortgage points and fees or high-cost mortgage thresholds.[166] The Bureau is not able to determine precisely how representative these data are of the overall retail mortgage market, however. The Bureau therefore did not rely on these data, although the overall patterns in these data and the general magnitudes of any effects align with the Bureau's general understanding of the level of loan originator compensation and the level of up-front charges in the market. This general understanding informs the Bureau's analysis and leads the Bureau to believe that the economic impact of these outcomes should be small. On the whole, the final rule will slightly reduce costs related to supplying these loans as well as compliance costs for covered persons as compared to the 2013 ATR Final Rule. The Bureau believes that consumers will benefit from slightly increased access to credit and lower costs on the affected loans, but in return will not receive the protections afforded to loans originated under the general ability-to-repay standards or to high-cost mortgages.

This provision of the rule may also alter the competitive dynamics between the wholesale channel and the retail channel. As noted above, the Bureau recognizes that an additive approach makes it more difficult for creditors to impose up-front charges and still remain under the qualified mortgage points and fees limits and the high-cost mortgage threshold. For certain loans originated through the brokerage channel, the inclusion of compensation paid by the creditor to the brokerage firm in the points and fees calculation may have the effect of denying the loan qualified mortgage status while a loan ostensibly similar in terms of interest rate and up-front charges but that has no broker commission because it is offered through the retail channel might be a qualified mortgage. However, for loans in the brokerage channel, this impact could be mitigated by having the consumer pay the broker directly, by shifting other origination charges into the rate, and/or by shifting from a settlement services provider affiliated with the creditor to a non-affiliated provider.

The major alternative that the Bureau considered to address the competitive impact of the final rule was including in points and fees compensation from creditors to their loan originator employees in retail transactions (either under an additive or netting approach). This alternative, however, also could have altered the nature of competition between retail and the wholesale channels. On the one hand, if this alternative had been implemented, fewer loans made through the retail channel would have fallen within the regulatory points and fees thresholds.[167] On the other hand, the compliance burden on creditors originating retail transactions would have been significant, which could have given the wholesale channel a competitive advantage over the retail channel due to the cost of complying with this alternative. As noted above, the Bureau's general understanding of the market suggests that this alternative would not materially change which loans are qualified mortgages in the retail channel. However, the Bureau received numerous industry comments asserting that counting loan officer compensation in retail transactions would impose a significant burden on the retail channel.[168] Each creditor originating loans through the retail channel would have to devise internal policies and systems regarding which components of loan officers' compensation (and that of any other employees occasionally performing some of the loan officers' functions) to include under the rule and a method of tracking such compensation in real time for the purpose of determining whether a particular loan is eligible for the qualified mortgage status or is a high-cost mortgage. The Bureau believes that the labor and investments to develop such systems would be substantial. As described above, the Bureau was also concerned that this alternative would have provided little benefit to consumers, in part due to the anomalies in counting individual loan originator compensation that is specific to the retail transaction as of the time that the interest rate is set.

The other major alternative discussed in the proposed rule would have permitted creditors to net origination charges against loan originator compensation paid to brokers (and creditors' own loan originator employees) to calculate the amount of loan originator compensation that is included in points and fees. As noted, under such an approach (as compared to the final rule), fewer loans originated through the wholesale channel would exceed the qualified mortgage and high-cost points and fees thresholds. In the wholesale context, comprehensive data that includes points and fees as well as loan originator compensation is also not readily available. However, as discussed above, the Bureau was concerned that such an approach would reduce the benefits to consumers of the qualified mortgage status and high-cost mortgage protections by allowing higher combined loan originator compensation and up-front points and fees. Particularly in markets that are not fully competitive or in transactions involving less sophisticated consumers or consumers who are less likely to shop for competitive pricing, the Bureau was concerned that the netting approach would provide greater flexibility to structure loan originator compensation to provide incentives for mortgage brokers to deliver more costly loans. In addition, the Bureau was concerned that such an approach would have created strong incentives for creditors and mortgage brokers to structure loan originator compensation to be paid

[166] The precise magnitudes of the effects depend critically on whether third-party charges are provided by an affiliate of the loan originator. Assuming that affiliates are not involved in the transaction, the rule has almost no effect, with fewer than 0.5% of loans in this sample dropping below the relevant thresholds. Under the assumption that affiliates provided all settlement services, roughly 6% of loans that would exceed the limits are projected to no longer do so once loan originator compensation is excluded. However, this figure is very likely an overestimate: Even for those creditors that use affiliates, it is rare that all settlement charges would be provided by affiliated third parties.

[167] The extent that payments from creditors to brokerage firms must cover overhead, which is not included in payments from creditor to their own employees, limits the degree to which this alternative could achieve a fully equal impact.

[168] The wholesale channel does not experience nearly the same burden due to this rule. Both the creditor to broker and the consumer to creditor fees are already routinely calculated by the industry.

through the creditor to take advantage of the netting approach, which is not available where the consumer pays the mortgage broker directly.

Other combinations of the additive approach, the netting approach, and the approach of excluding all compensation in either channel are also possible; the impacts are derived as combinations of the ones discussed here.

2. Exemptions From Ability-to-Repay Requirements

As described in the Section 1022 Analysis of the 2013 ATR Final Rule, there are a number of situations where creditors may engage in lending with too little regard for the consumer's ability to repay. The 2013 Final ATR Rule is designed to minimize such activity by ensuring proper documentation and verification related to extensions of credit and by requiring consideration of a number of factors including the consumer's debt-to-income ratio and credit history. Creditors who fail to follow any of these requirements, or who extend credit without a ''reasonable and good faith determination'' of the consumer's ability to repay, are subject to liability.[169] However, as described above, the Bureau was concerned that the ability-to-repay requirements adopted in the 2013 ATR Final Rule would undermine or frustrate application of the uniquely tailored underwriting requirements employed by certain creditors and programs, and would require a significant diversion of resources to compliance, thereby significantly reducing access to credit. The Bureau was also concerned that some of these creditors would not have the resources to implement and comply with the ability-to-repay requirements, and may have ceased or severely limited extending credit to low- to moderate-income consumers, which would result in the denial of responsible, affordable mortgage credit. The exemptions from the ability-to-repay requirements are designed to eliminate these requirements and thereby to limit creditors' costs and protect credit availability in carefully defined circumstances, namely loans or loan programs that serve certain consumers or communities and that typically assess repayment ability in ways that do not necessarily comport with the requirements of the Act and the 2013 ATR Final Rule.

As described earlier, mortgage lending by community-focused creditors, programs operated by housing finance agencies, nonprofit organizations, and housing stabilization programs, varies widely in the form of financing, the products offered, and the precise nature of underwriting. In particular, the Bureau understands that many of these creditors do not use documentation and verification procedures closely aligned with the requirements of the 2013 ATR Final Rule or consider all of the underwriting factors specified in the rule. The benefits of the final rule derive from eliminating the costs of imposing these requirements on these particular extensions of credits and assuring that credit remains available through these programs without regard to the rule's underwriting factors. Access to credit is a specific concern for the populations generally served by these lenders and programs.

As explained in the 2013 ATR Final Rule, in general, consumers and others could be harmed by this action as it removes particular consumer protections and could allow some deleterious lending to occur. However, in all of the cases discussed above, the Bureau believes that the community-focused mission of the creditor organizations and/or programs through which credit is extended, the close interaction between creditors and consumers in these instances, and other safeguards (including government monitoring of certain categories and the origination thresholds for the general nonprofit category) should mitigate any potential harms to consumers and costs from the rule.

Data regarding the exact scope of lending through these channels are limited, as are data regarding the performance of these loans. There are 51 HFAs and approximately 1,000 CDFIs, 62 percent of which are classified as Community Development (CD) Loan Funds, 22 percent as CD Credit Unions, while the rest are CD Banks, Thrifts, or CD Venture Capital Funds.[170] There are 233 501(c)(3) nonprofit agencies and nonprofit instrumentalities of government in the U.S. that are authorized to provide secondary financing,[171] 267 creditors certified by HUD as Community Housing Development Organizations (CHDOs) in connection with HUD's HOME Investment Partnership Program,[172] and 231 organizations certified as Downpayment Assistance through Secondary Financing Providers.[173] The Bureau is not aware and commenters did not provide a comprehensive list of these institutions. However, the Bureau believes that there may be substantial overlap among these institutions. A large number of creditors participate in the housing stabilization programs covered by the final rule.

Data regarding the number or volume of loans made by housing finance agencies and community-focused lending programs is limited. There is some data suggesting that HFA bonds funded approximately 67,000 loans in 2010 with a value of just over $8 billion.[174] Data regarding CDFIs indicate that these institutions funded just under $4 billion in loans; however, data on the type of housing supported is unavailable.[175] Lending at CHDOs totaled $64 million in 2011 with just under 500 loans.[176]

The Bureau had proposed an exemption to the ability-to-repay requirements for refinancing programs offered by the Department of Housing and Urban Development (HUD), the Department of Veterans Affairs (VA), or the U.S. Department of Agriculture (USDA). Similarly, the Bureau had proposed an exemption to the ability-to-repay requirements for certain GSE refinancing programs. However, as noted above, the Bureau has concluded after further deliberation that the proposed exemptions from the ability-to-repay requirements are unnecessary because, even absent an exemption from the ability-to-repay requirements, FHA,

[169] The liability regime extends beyond creditors. As amended by section 1413 of the Dodd-Frank Act, TILA provides that when a creditor, an assignee, other holder or their agent initiates a foreclosure action, a consumer may assert a violation of TILA section 129C(a) ''as a matter of defense by recoupment or setoff.'' TILA section 130(k). There is no time limit on the use of this defense and the amount of recoupment or setoff is limited, with respect to the special statutory damages, to no more than three years of finance charges and fees. The impacts of the liability regime applicable to covered mortgages are discussed in more detail in the 1022 analysis for the 2013 ATR Final Rule.

[170] *See* U.S. Dep't of the Treas., Community Development Financial Institutions Fund, *http://www.cdfifund.gov/docs/certification/cdfi/CDFI List-07-31-12.xls.*

[171] *See* U.S. Dep't of Hous. and Urban Development: Nonprofits, *https://entp.hud.gov/idapp/html/f17npdata.cfm.*

[172] Includes 2011 data for institutions with CHDO reservations and CHDO loans without a rental tenure type. *See* U.S. Dep't of Hous. and Urban Development: HOME Participating Jurisdiction's Open Activities Reports, *http://www.hud.gov/offices/cpd/affordablehousing/reports/open/.*

[173] Includes data for institutions shown to offer secondary financing. *See* U.S. Dep't of Hous. and Urban Development: Nonprofits, *https://entp.hud.gov/idapp/html/f17npdata.cfm.*

[174] *See* National Council of State Housing Agencies, *State HFA Factbook* (2010), *http://www.ncsha.org/story/ncsha-releases-comprehensive-survey-hfa-program-activity.*

[175] *See* U.S. Dep't of the Treas., Community Development Financial Institutions Fund: Awardees/Allocatees, *http://www.cdfifund.gov/awardees/db/basicSearchResults.asp.*

[176] *See* U.S. Dep't of Hous. and Urban Development: HOME Participating Jurisdiction's Open Activities Reports, *http://www.hud.gov/offices/cpd/affordablehousing/reports/open.*

VA, and USDA loans, including refinancings, as well as GSE refinancings, are given qualified mortgage status under the Bureau's 2013 ATR Final Rule. Under the temporary category of qualified mortgages in § 1026.43(e)(4), the final rule already incorporates the refinancing programs' specific underwriting criteria and affords these loans a presumption (in some cases, conclusive) of compliance with the ability-to-repay requirements, so long as they meet certain product feature requirements and limitations on points and fees. The small difference between the proposed exemption and the 2013 ATR Final Rule temporary category for QMs involves loan features (*e.g.,* negative amortization and interest only features) and the cap on points and fees under § 1026.43(e)(2). Under the 2013 ATR Final Rule, loans with those features or above the points and fees threshold (that otherwise meet the conditions of the QM definition) cannot be originated as qualified mortgages and therefore must meet the ability-to-repay requirements, while under the proposed exemption they would have been exempted from those requirements as well. The Bureau believes that very few refinancings would be excluded on these grounds and therefore that these restrictions should not impose any additional meaningful costs on creditors or impede consumers' access to responsible, affordable mortgage credit.

Qualified mortgage refinancings that trigger the threshold for higher-priced mortgage loans are also another small area of difference: under the 2013 ATR Final Rule, these loans have a rebuttable presumption of compliance with the ability-to-repay requirements while under the exemption there would have been no such requirements. As described, costs for covered persons offering these loans could be slightly higher. However, as discussed above, in light of the history of refinancings, the Bureau believes that it is a meaningful benefit to consumers to preserve their ability to seek redress in the event of abuse.

3. Extension of Qualified Mortgage Status

The benefits to covered persons from extending qualified mortgage status to certain loans made by smaller creditors and held on portfolio also derive from maintaining access to credit and limiting potential increases in the costs of these loans. By granting creditors that qualify under the new qualified mortgage definition a conclusive or rebuttable presumption of compliance with the ability-to-repay provisions, the final rule limits the legal liability of these creditors and most expected litigation costs. The final rule may also provide greater flexibility with regard to certain documentation, verification, and underwriting practices in certain circumstances.[177] These cost reductions in turn could enhance the willingness of such creditors to make these loans or reduce the amount the creditors would otherwise charge for these loans.[178] Consumers, too, will benefit to the extent that the expanded qualified mortgage status makes creditors more willing to continue extending such credit and to do so at a lower price than they might charge for non-qualified mortgages under the new regulations. In return, however, consumers will have narrower grounds on which to challenge any violations of the ability-to-repay rules as discussed in more detail in the Section 1022 analysis of the 2013 Final ATR Rule.

Given the lower default and delinquency rates at these smaller community-focused institutions, the avoided costs related to liability and litigation are likely small. However, the lower default and delinquency rates at these institutions, the relationship lending that they engage in, and restrictions on reselling the loans on the secondary market for at least three years, together also suggest that the risk of consumer harm (and therefore the costs of this provisions) are also very small.[179] While the mathematical impacts of litigation costs/risks may be limited, the Bureau believes that the broader impacts on access to credit could be significant particularly in individual communities.

Based on data from 2011, roughly 9,200 institutions with approximately 450,000 loans on portfolio are likely to be affected by the extension of qualified mortgages for certain small creditors.[180] Based on the Bureau's estimates, on average, 16.7 percent of portfolio loans at these institutions are estimated to have a DTI ratio above 43 percent. For the subset of these loans that also do not contain any of the prohibited features for the general definition for qualified mortgages (assuming other conditions are met), the final rule grants the creditor a conclusive or rebuttable presumption of compliance with the ability-to-repay requirements. The Bureau is unable to estimate the percentage of these loans that would not qualify for the temporary expansion of the qualified mortgage definition in the final rule under § 1026.43(e)(4). Similarly, the Bureau is unable to estimate the number of balloon mortgages originated by lenders not operating in rural areas that are eligible for qualified mortgage status under the final rule's temporary provision.

Similar tradeoffs are involved in the increase in the qualified mortgage threshold from 1.5 percentage points above the average prime offer rate (APOR) to 3.5 percentage points above APOR for first lien mortgages originated and held by small creditors and for the qualified balloon mortgages originated and held by small creditors predominantly operating in rural or underserved areas. For loans in this APR range, whether they meet the definition of qualified mortgage under the 2013 Final ATR Rule or under the new definitions provided in this final rule, the presumption of compliance with the ability-to-repay requirements would be strengthened. The Bureau estimates that roughly 8–10 percent of portfolio loans at these institutions are likely to be affected by this change. Strengthening the presumption of compliance for these loans will benefit consumers and/or covered persons to the extent doing so improves credit access or reduces costs. Strengthening the presumption will have a cost to consumers to the extent consumers who find themselves unable to afford their

[177] For example, the final rule requires that small creditors assess either the debt-to-income ratio or the residual income of the borrower, but does not require that the consumer's DTI not exceed 43 percent as determined pursuant to appendix Q nor that the loan be eligible for purchase, guarantee, or insurance by the GSEs or by specified federal agencies.

[178] To the extent that the cost advantage is material, this provision could give some smaller institutions a slight advantage over lenders not eligible to make qualified mortgages using this definition.

[179] The possibility that small creditors qualifying for this exemption can make certain mortgages as qualified mortgages, while their larger competitors can only make these loans subject to the ability-to-repay provisions, may allow them to offer these loans at lower rates. However, as discussed in the 2013 ATR Final Rule, any effects on pricing are likely to be small.

[180] The estimates in this analysis are based upon data and statistical analyses performed by the Bureau. To estimate counts and properties of mortgages for entities that do not report under HMDA, the Bureau has matched HMDA data to Call Report data and MCR data and has statistically projected estimated loan counts for those depository institutions that do not report these data either under HMDA or on the NCUA call report. The Bureau has projected originations of higher-priced mortgage loans for depositories that do not report HMDA in a similar fashion. These projections use Poisson regressions that estimate loan volumes as a function of an institution's total assets, employment, mortgage holdings, and geographic presence. Neither HMDA nor the Call Report data have loan level estimates of the DTI. To estimate these figures, the Bureau has matched the HMDA data to data on the HLP dataset provided by the FHFA. This allows estimation of coefficients in a probit model to predict DTI using loan amount, income, and other variables. This model is then used to estimate DTI for loans in HMDA.

mortgage, and would otherwise be able to make out a claim and recover their losses, would be unable to do so under the expanded safe harbor.

B. Potential Specific Impacts of the Final Rule

1. Potential Impact on Consumer Access to Consumer Financial Products or Services

The Bureau does not anticipate that the final rule would reduce consumers' access to consumer financial products and services. Rather, as discussed above, the Bureau believes that the final rule would in fact enhance certain consumers' access to mortgage credit as compared to the 2013 ATR Final Rule. The Bureau believes that the exclusion of certain compensation from the calculation of points and fees allows more mortgages under the qualified mortgage and high-cost mortgage thresholds; the exemption from the ability-to-repay requirements should facilitate lending under various programs and by various creditors; and, the new and expanded qualified mortgage definitions should also expand responsible lending.

2. Depository Institutions and Credit Unions With $10 Billion or Less in Total Assets, as Described in Section 1026

The Bureau believes the final rule will have differential impacts on some depository institutions and credit unions with $10 billion or less in total assets as described in Section 1026. The depository institutions and credit unions that are CDFIs, and are therefore covered under the exemption from the ability-to-repay requirements, and the institutions covered by new definition of qualified mortgages and the higher-rate threshold for small creditor portfolio loans are all in this group and are therefore uniquely impacted by the rule as discussed above.

3. Impact of the Provisions on Consumers in Rural Areas

The final rule will have some differential impacts on consumers in rural areas. In these areas, a greater fraction of loans are made by smaller institutions and carried on portfolio and therefore the small creditor portfolio exemption would be likely to have greater impacts. The Bureau understands that mortgage loans in these areas and by these institutions are less standardized and often cannot be sold into the secondary market. These differences may result in slightly higher interest rates on average for loans to rural consumers and more higher priced mortgage loans. By making it easier for loans held in portfolio by certain institutions to receive qualified mortgage status and by raising the rebuttable presumption threshold for those loans, the final rule will likely have a greater relative effect on rural consumers than on their non-rural counterparts: more loans will meet the definitions for qualified mortgages and within that group, more loans will have the safe harbor presumption of compliance with the ability-to-repay requirements. To the extent that these changes expand access to credit, rural consumers will benefit. While the relationship model of lending prevalent in this area makes both delinquency and litigation less likely overall, these changes will also limit some of the protections for these consumers as well.[181]

VIII. Regulatory Flexibility Act Analysis

A. Overview

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct an initial regulatory flexibility analysis (IRFA) and a final regulatory flexibility analysis (FRFA) of any rule subject to notice-and-comment rulemaking requirements.[182] These analyses must ''describe the impact of the proposed rule on small entities.'' [183] An IRFA or FRFA is not required if the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities.[184] The Bureau also is subject to certain additional procedures under the RFA involving the convening of a panel to consult with small business representatives prior to proposing a rule for which an IRFA is required.[185]

The final rule amends Regulation Z, which implements the Truth in Lending Act (TILA) and is related to a final rule published in the **Federal Register** in January 2013 (78 FR 6408) (2013 ATR Final Rule). That final rule implements certain amendments to TILA that were added by sections 1411, 1412, and 1414 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), which created new TILA section 129C. These changes were made in response to the recent foreclosure crisis to address certain lending practices (such as low- or no-documentation loans or underwriting mortgages without including any principal repayments in the underwriting determination) that led to consumers having mortgages they could not afford, thereby contributing to high default and foreclosure rates. Among other things, the Dodd-Frank Act requires creditors to make a reasonable, good faith determination of a consumer's ability to repay any consumer credit transaction secured by a dwelling (excluding an open-end credit plan, timeshare plan, reverse mortgage, or temporary loan) and establishes certain protections from liability under this provision for ''qualified mortgages.''

As discussed above, the Bureau believes that the 2013 ATR Final Rule should be modified to address potential adverse consequences on certain narrowly-defined categories of lending programs. Specifically, the final rule adopts certain amendments to the 2013 ATR Final Rule implementing these requirements, including exemptions for certain nonprofit and community-focused lending creditors and certain homeownership stabilization and foreclosure prevention programs. The final rule also creates a new category of qualified mortgages, similar to the one for rural balloon-payment loans, for loans without balloon-payment features that are originated and held on portfolio by small creditors. The new category will not be limited to creditors that operate predominantly in rural or underserved areas, but will use the same general size thresholds and other criteria as the rural or underserved balloon-payment rules. In light of the fact that small creditors often have higher costs of funds than larger creditors, the final rule also increases the threshold separating safe harbor and rebuttable presumption qualified mortgages for balloon-payment qualified mortgages, the new small portfolio qualified mortgages, and balloon-payment qualified mortgages originated under the new temporary two-year balloon mortgage provision. Finally, the final rule provides additional clarifications and exclusions regarding

[181] Relationship lending refers to underwriting decisions predicated on more tacit information and personal relationships, in particular, relative to more automated and formula-based forms of underwriting.

[182] 5 U.S.C. 601 *et. seq.*

[183] 5 U.S.C. 603(a); 5 U.S.C. 604(a). For purposes of assessing the impacts of the proposed rule on small entities, ''small entities'' is defined in the RFA to include small businesses, small not-for-profit organizations, and small government jurisdictions. 5 U.S.C. 601(6). A ''small business'' is determined by application of Small Business Administration regulations and reference to the North American Industry Classification System (NAICS) classifications and size standards. 5 U.S.C. 601(3). A ''small organization'' is any ''not-for-profit enterprise which is independently owned and operated and is not dominant in its field.'' 5 U.S.C. 601(4). A ''small governmental jurisdiction'' is the government of a city, county, town, township, village, school district, or special district with a population of less than 50,000. 5 U.S.C. 601(5).

[184] 5 U.S.C. 605(b).

[185] 5 U.S.C. 609.

the inclusion of loan originator compensation in the points and fees calculation for all categories of qualified mortgage.

In the proposal, the Bureau certified that the rule would not have a significant economic impact on a substantial number of small entities and therefore did not prepare an IRFA. Approximately 100 commenters argued that the Bureau should conduct a SBREFA panel to learn more about how the rule will impact the thousands of small business entities that originate mortgage loans. These commenters noted that while the Bureau stated that an initial regulatory flexibility analysis (IRFA) was not necessary under the Regulatory Flexibility Act (RFA) because the proposal would not have a significant economic impact on a substantial number of small entities, the Bureau's own methodology showed that the rule would apply to 9,373 small entities out of 14,194 total entities that originate mortgage loans. These commenters contended that the Bureau use its authority under the Dodd-Frank Act to delay the effective date of the 2013 ATR Final Rule and conduct further analysis of the mortgage loan origination market and how loan originators are currently assessing and determining consumers' ability to repay.[186]

While the Bureau acknowledges that the exemption applies to many small entities, this does not imply that it has a significant impact on a substantial number of small entities. Further, the commenters provided little reasoning and no data to support the claim that the rule would have such an effect. The Bureau believes that the final rule will not have a significant impact on a substantial number of small entities and therefore neither a SBREFA panel nor a FRFA is required.

The analysis below evaluates the potential economic impact of the final rule on small entities as defined by the RFA. The analysis generally examines the regulatory impact of the provisions of the final rule against the baseline of the 2013 ATR Final Rule published in January 2013, however some of the discussion includes consideration of alternative baselines. As a result of this analysis, the Bureau certifies that the final rule would not have a significant economic impact on a substantial number of small entities.

B. Number and Classes of Affected Entities

The final rule will apply to all creditors that extend closed-end credit secured by a dwelling, including real property attached to a dwelling, subject to certain exemptions. All small entities that extend these loans are potentially subject to at least some aspects of the final rule. This rule may impact small businesses, small nonprofit organizations, and small government jurisdictions. A ''small business'' is determined by application of SBA regulations and reference to the North American Industry Classification System (NAICS) classifications and size standards.[187] Under such standards, depository institutions with $175 million or less in assets are considered small; other financial businesses are considered small if such entities have average annual receipts (*i.e.,* annual revenues) that do not exceed $7 million. Thus, commercial banks, savings institutions, and credit unions with $175 million or less in assets are small businesses, while other creditors extending credit secured by real property or a dwelling are small businesses if average annual receipts do not exceed $7 million.

The Bureau can identify through data under the Home Mortgage Disclosure Act, Reports of Condition and Income (Call Reports), and data from the National Mortgage Licensing System (NMLS) the approximate numbers of small depository institutions that will be subject to the final rule. Origination data is available for entities that report in HMDA, NMLS or the credit union call reports; for other entities, the Bureau has estimated their origination activities using statistical projection methods.

The following table provides the Bureau's estimate of the number and types of entities to which the rule will apply:

Category	NAICS Code	Total entities	Small entities	Entities that originate any mortgage loans [b]	Small entities that originate any mortgage loans
Commercial Banking	522110	6,505	3,601	[a] 6,307	[a] 3,466
Savings Institutions	522120	930	377	[a] 922	[a] 373
Credit Unions [c]	522130	7,240	6,296	[a] 4,178	[a] 3,240
Real Estate Credit [d] [e]	522292	2,787	2,294	2,787	[a] 2,294
Total	.....	17,462	12,568	14,194	9,373

Source: 2011 HMDA, Dec 31, 2011 Bank and Thrift Call Reports, Dec 31, 2011 NCUA Call Reports, Dec 31, 2011 NMLSR Mortgage Call Reports.

[a] For HMDA reporters, loan counts from HMDA 2011. For institutions that are not HMDA reporters, loan counts projected based on Call Report data fields and counts for HMDA reporters.

[b] Entities are characterized as originating loans if they make one or more loans.

[c] Does not include cooperativas operating in Puerto Rico. The Bureau has limited data about these institutions or their mortgage activity.

[d] NMLSR Mortgage Call Report (MCR) for 2011. All MCR reporters that originate at least one loan or that have positive loan amounts are considered to be engaged in real estate credit (instead of purely mortgage brokers). For institutions with missing revenue values, the probability that institution was a small entity is estimated based on the count and amount of originations and the count and amount of brokered loans.

[e] Data do not distinguish nonprofit from for-profit organizations, but Real Estate Credit presumptively includes nonprofit organizations.

It is difficult to determine the number of small nonprofits that would be subject to the regulation. Nonprofits do not generally file Call Reports or HMDA reports. As explained in part II above, as of November 2012 there are 233 nonprofit agencies and nonprofit instrumentalities of government in the U.S. that are authorized by HUD to provide secondary financing,[188] 267 institutions designated as Community Housing Development Organizations that provided credit in 2011, and 231 institutions designated as Downpayment Assistance through

[186] 78 FR 6663–6666.

[187] 5 U.S.C. 601(3). The current SBA size standards are located on the SBA's Web site at *http://www.sba.gov/content/table-small-business-size-standards.*

[188] *See* U.S. Dep't of Hous. and Urban Development: Nonprofits, *https://entp.hud.gov/idapp/html/f17npdata.cfm.*

Secondary Financing Providers. A comprehensive list of these institutions is not available; however the Bureau believes that there may be substantial overlap among these institutions and that most of these institutions would qualify as small entities.

Also, as of July 2012 there were 999 organizations designated by the Treasury Department as CDFIs, 356 of which are depository institutions or credit unions counted above. Among the remaining, some are nonprofits and most likely small.[189]

C. Clarification Regarding Loan Originator Compensation in the Points and Fees Calculation

As discussed in detail above, the Dodd-Frank Act requires creditors to include all compensation paid directly or indirectly by a consumer or creditor to a mortgage originator from any source, including a mortgage originator that is also the creditor in a table-funded transaction, in the calculation of points and fees. The statute does not express any limitation on this requirement, and thus, the Bureau adopted in the 2013 ATR Final Rule that loan originator compensation be treated as additive to up-front charges paid by the consumer and the other elements of points and fees and that compensation is added as it flows downstream to the loan originator.

The final rule provides that payments by consumers to mortgage brokers need not be counted as loan originator compensation where such payments already have been included in points and fees as part of the finance charge. The final rule also provides that compensation paid by a mortgage broker to its employee loan originator need not be included in points and fees. In the final rule, compensation paid by a creditor to a mortgage broker is included in points and fees in addition to any origination charges paid by a consumer to the creditor. Compensation paid by a creditor to its own loan originator employees need not be included in points and fees.

The statute requires loan originator compensation to be treated as additive to the other elements of points and fees and the 2013 ATR Final Rule adopted this approach. This places a burden on small creditors, since it makes it more likely that mortgage loans will not be eligible as qualified mortgages under the ability-to-repay rules or will be classified as high-cost mortgages for purposes of HOEPA. The Bureau's exercise of its exception and adjustment authority in the final rule, however, will reduce burden on small entities and facilitate compliance. Compared to the January 2013 baseline, where such compensation is included in the points and fees calculation, the final rule reduces burden on certain small entities: for retail originators, fewer loans will exceed the points and fees limits for qualified mortgages and high cost mortgages, and firms will face lowered compliance costs.[190]

D. Exemptions from the Ability-to-Repay Requirements

The provisions related to community-focused lending programs discussed above all provide exemptions from the ability-to-repay requirements. Measured against the baseline of the Bureau's 2013 ATR Final Rule, these provisions impose either no or insignificant additional burdens on small entities. More specifically, these provisions will reduce the burdens associated with implementation costs, additional underwriting costs, and compliance costs stemming from the ability-to-repay requirements.

Section 1026.43(a)(3)(iv) provides that an extension of credit made pursuant to a program administered by a housing finance agency, as defined by 24 CFR 266.5, is exempt from the requirements of § 1026.43(c) through (f). For any housing finance agencies and their partner creditors that meet the definition of ''small entity,'' this provision will remove the burden of having to modify the underwriting practices associated with these programs to implement the ability-to-repay requirements. This provision will also remove the burden to small entities of having to develop and maintain policies and procedures to monitor compliance with the ability-to-repay requirements.

The final rule also exempts from the ability-to-repay requirements an extension of credit made by a creditor designated as a Community Development Financial Institution, a Downpayment Assistance through Secondary Financing Provider, or a Community Housing Development Organization (CHDO) if the CHDO meets certain additional criteria. This provision will remove the burden to small entities of having to implement the ability-to-repay requirements. This provision will also remove the burden to small entities of having to develop and maintain policies and procedures to monitor compliance with the ability-to-repay requirements. Regulatory burdens may be associated with obtaining and maintaining one of the designations required to qualify for the exemption. However, this decision is voluntary and the Bureau presumes that a small entity would not do so unless the burden reduction resulting from the exemption outweighed the additional burden imposed by obtaining and maintaining the designation. Thus, additional burdens would still be part of an overall burden reduction.

The final rule also exempts from the ability-to-repay requirements extensions of credit made by a creditor with a tax exemption ruling or determination letter from the Internal Revenue Service under section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3) provided that: during the calendar year preceding receipt of the consumer's application, the creditor extended credit secured by a dwelling no more than 200 times; during the calendar year preceding receipt of the consumer's application, the creditor extended credit secured by a dwelling only to consumers with income that did not exceed the low- and moderate-income household limits; the extension of credit is to a consumer with income that does not exceed the above limit; and, the creditor determines, in accordance with written procedures, that the consumer has a reasonable ability to repay the extension of credit.

For eligible entities, this provision will remove the burden of complying with the ability-to-repay requirements. This provision will also remove the burden to small entities of having to develop and maintain policies and procedures to monitor compliance with the ability-to-repay requirements in the 2013 ATR Final Rule. While eligible nonprofit creditors will need to maintain documentation of their own procedures regarding the determination of a consumer's ability to repay, the Bureau believes that such small nonprofits already have written policies and procedures. In any case, the decision to use the exemption is voluntary and entities are expected to use it only if reduces overall burden. Regulatory burdens may be associated with obtaining and maintaining the 501(c)(3) designation required to qualify for the exemption. However, this decision is voluntary and the Bureau presumes that a small entity would not do so unless the burden reduction resulting from the exemption outweighed the additional burden imposed by obtaining and maintaining

[189] *See* U.S. Dep't of the Treas., Community Development Financial Institutions Fund, *http://www.cdfifund.gov/docs/certification/cdfi/CDFIList-07–31–12.xls.*

[190] The Bureau notes that the ability-to-repay requirements as well as the rules applying to high-cost mortgages generally apply to creditors and not to other classes of small entities including mortgage brokers.

the designation. Thus, additional burdens would still be part of an overall burden reduction.

The final rule provides that an extension of credit made pursuant to a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008 is exempt from the ability-to-repay requirements. This provision will remove the burden to participating small entities of having to modify the underwriting practices associated with these programs to implement the ability-to-repay requirements. This provision will also remove the burden to small entities of having to develop and maintain policies and procedures to monitor compliance with these ability-to-repay requirements.

E. Portfolio Loans Made by Small Creditors and Balloon-Payment Qualified Mortgages

As discussed above, the Bureau is finalizing certain amendments to the 2013 ATR Final Rule, including an additional definition of a qualified mortgage for certain loans made and held in portfolio by small creditors. The new category includes certain loans originated by small creditors that: (1) Have total assets less than $2 billion at the end of the previous calendar year; and (2) together with all affiliates, originated 500 or fewer covered transactions, secured by first-liens during the previous calendar year. The $2 billion asset threshold in the definition will be adjusted annually based on the year-to-year change in the average of the Consumer Price Index for Urban Wage Earners and Clerical Workers, not seasonally adjusted. These loans must generally conform to the requirements under the general definition of a qualified mortgage in § 1026.43(e)(2), except that a loan with a consumer debt-to-income ratio higher than 43 percent could be a qualified mortgage if all other criteria are met. Small creditors are required to consider the consumer's debt-to-income ratio or residual income in underwriting the loans, but are not required to follow appendix Q or subject to any specific threshold.

This provision would reduce burden on small creditors by removing the 43 percent debt-to-income limitation for qualified mortgages, as well as providing more flexibility in the assessment of debt-to-income ratios. At the small creditors identified, 16.7 percent of mortgage loans on portfolio are estimated to have a debt to income ratios above 43 percent. For these loans, the final rule grants creditors a presumption of compliance with the ability-to-repay requirements; rough estimates indicate that three quarters of these loans will gain a conclusive presumption and the remaining loans will gain the rebuttable presumption. The final rule also temporarily allows small creditors that do not operate predominantly in rural or underserved areas to offer balloon-payment qualified mortgages, with the same presumptions of compliance, if they hold the loans in portfolio.

The Bureau also is allowing small creditors to charge a higher annual percentage rate for first-lien qualified mortgages in the new category and still benefit from a conclusive presumption of compliance or ''safe harbor.'' In addition, the Bureau also is allowing small creditors operating predominantly in rural or underserved areas to offer first-lien balloon loans with a higher annual percentage rate and still benefit from a conclusive presumption of compliance with the ability-to-repay rules or ''safe harbor.'' The increase in the threshold from the average prime offer rate (APOR) plus 1.5 percentage points to APOR plus 3.5 percentage points will reduce burden for the loans at these institutions between these rates, as these loans will now qualify for a conclusive, rather than a rebuttable presumption.

The regulatory requirement to make a reasonable and good faith determination based on verified and documented evidence that a consumer has a reasonable ability to repay may entail litigation risk for small creditors. It is difficult to estimate the reduction in potential future liability costs associated with the changes. However, the Bureau notes that lending practices at smaller institutions are often based on a more personal relationship based model and that historically, delinquency rates on mortgages at smaller institutions are lower than the average in the industry. The Bureau believes that small creditors have historically engaged in responsible mortgage underwriting that includes thorough and thoughtful determinations of consumers' ability to repay, at least in part because they bear the risk of default associated with loans held in their portfolios. The Bureau also believes that because small creditors' lending model is based on maintaining ongoing, mutually beneficial relationships with their customers, they therefore have a more comprehensive understanding of their customers' financial circumstances and are better able to assess ability to repay than larger creditors. As such, the expected litigation costs from the ability-to-repay provisions of the 2013 ATR Final Rule, and therefore the reduced burden from this final rule, should be small.

The Bureau acknowledges the possibility that this final rule may increase small creditor burden to the extent that creditors need to maintain records relating to eligibility for the exemption, but the Bureau believes that these costs are negligible, as creditor asset size and origination activity are data that all depository institutions and credit unions are likely to maintain for routine business or supervisory purposes. Thus, the Bureau believes that the burden reduction stemming from a reduction in liability costs would outweigh any potential recordkeeping costs, resulting in overall burden reduction. Small entities for which such cost reductions are outweighed by additional record keeping costs may choose not to utilize the exemption.

F. Conclusion

Each element of this final rule results in an economic burden reduction for these small entities. The exemptions for nonprofit creditors would lessen any economic impact resulting from the ability-to-repay requirements. The exemptions for homeownership stabilization and foreclosure prevention programs would also soften any economic impact on small entities extending credit pursuant to those programs. The new categories of qualified mortgage would make it easier for small entities to originate qualified mortgages. The Bureau's clarifications ensuring consumer-paid compensation to brokers is counted only once and the exclusion of retail loan officer and broker employee compensation will reduce burden on small entities and make it more likely that mortgage loans will be eligible for a presumption of compliance as qualified mortgages under the ability-to-repay rules and not be classified as high-cost mortgages for purposes of HOEPA. While all of these provisions may entail some additional recordkeeping costs, the Bureau believes that these costs are minimal and outweighed by the cost reductions resulting from the final rule. Small entities for which such cost reductions are outweighed by additional record keeping costs may choose not to utilize the exemptions.

Certification

Accordingly, the undersigned certifies that this proposal will not have a significant economic impact on a substantial number of small entities.

IX. Paperwork Reduction Act Analysis

Certain provisions of this final rule contain ''collection of information''

requirements within the meaning of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (Paperwork Reduction Act or PRA). On January 30, 2013, the Bureau published notice of the proposed rule in the **Federal Register** (78 FR 6622). The Bureau received no PRA-related comments on the information collections in § 1026.43(c).

This final rule amends 12 CFR part 1026 (Regulation Z), which implements the Truth in Lending Act (TILA). Regulation Z currently contains collections of information approved by the Office of Management and Budget (OMB). The Bureau's OMB control number for Regulation Z is 3170–0015. The PRA (44 U.S.C. 3507(a), (a)(2) and (a)(3)) requires that a Federal agency may not conduct or sponsor a collection of information unless OMB approved the collection under the PRA and the OMB control number obtained is displayed. Further, notwithstanding any other provisions of law, no person is required to comply with, or is subject to any penalty for failure to comply with, a collection of information that does not display a currently valid OMB control number (44 U.S.C. 3512). The collection of information contained in this rule, and identified as such, has been submitted to OMB for review under section 3507(d) of the PRA.

A. Overview

As described below, the final rule amends the collections of information currently in Regulation Z to implement amendments to TILA made by the Dodd-Frank Act. This final rule is related to the Ability-to-Repay/Qualified Mortgage final rule (2013 ATR Final Rule) published in the **Federal Register** in January 2013 (78 FR 6408). The 2013 ATR Final Rule implements sections 1411, 1412, and 1414 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (the Dodd-Frank Act), which creates new TILA section 129C. Among other things, the Dodd-Frank Act requires creditors to make a reasonable, good faith determination, based on verified and documented information, that the consumer will have a reasonable ability to repay any consumer credit transaction secured by a dwelling (excluding an open-end credit plan, timeshare plan, reverse mortgage, or temporary loan), including any mortgage-related obligations (such as property taxes), and establishes certain protections from liability under this requirement for ''qualified mortgages.'' TILA section 129C(a); 15 U.S.C. 1639c(a). The stated purpose of the Dodd-Frank Act ability-to-repay requirement is to assure that consumers are offered and receive residential mortgage loans on terms that reasonably reflect their ability to repay the loans and that are not understandable and not unfair, deceptive or abusive. TILA section 129B(a)(2); 15 U.S.C. 1639b(a)(2). Prior to the Dodd-Frank Act, existing Regulation Z provided ability-to-repay requirements for high-cost and higher-priced mortgage loans. The Dodd-Frank Act expanded the scope of the ability-to-repay requirement to cover all residential mortgage loans with its scope.

The 2013 ATR Final Rule establishes standards for complying with the ability-to-repay requirement, including defining ''qualified mortgage.'' In addition to the ability-to-repay and qualified mortgage provisions, the 2013 ATR Final Rule implements the Dodd-Frank Act limits on prepayment penalties and lengthens the time creditors must retain records that evidence compliance with the ability-to-repay and prepayment penalty provisions.

This final rule adopts certain amendments to the 2013 ATR Final Rule implementing these ability-to-repay requirements, including exemptions for certain community-focused creditors, housing finance agencies, nonprofit organizations and housing stabilization programs; an additional definition of a qualified mortgage for certain loans made and held in portfolio by small creditors that have total assets less than $2 billion at the end of the previous calendar year and, together with all affiliates, originated 500 or fewer first-lien covered transactions during the previous calendar year. The final rule also temporarily allows small creditors that do not operate predominantly in rural or underserved areas to offer balloon-payment qualified mortgages if they hold the loans in portfolio. The Bureau also is allowing small creditors to charge a higher annual percentage rate for first-lien qualified mortgages in the new category and still benefit from a conclusive presumption of compliance or ''safe harbor,'' and to allow small creditors operating predominantly in rural or underserved areas to offer first-lien balloon loans with a higher annual percentage rate and still benefit from a conclusive presumption of compliance with the ability-to-repay rules or ''safe harbor.''

The final rule also provides exceptions to the 2013 ATR Final Rule, which implements the statute's inclusion of loan originator compensation in points and fees. Specifically, in the final rule, payments by consumers to mortgage brokers need not be counted as loan originator compensation where such payments already have been included in points and fees as part of the finance charge. In addition, compensation paid by a mortgage broker to its employee loan originator need not be included in points and fees, nor does compensation paid by a creditor to its own loan originator employees. However, consistent with the statute and 2013 ATR Final Rule, compensation paid by a creditor to a mortgage broker continues to be included in points and fees in addition to any origination charges paid by a consumer to the creditor.

The information collection in the final rule is required to provide benefits for consumers and would be mandatory. *See* 15 U.S.C. 1601 *et seq.;* 12 U.S.C. 2601 *et seq.* Because the Bureau does not collect any information under the final rule, no issue of confidentiality arises. The likely respondents would be depository institutions (*i.e.,* commercial banks, savings institutions and credit unions) and non-depository institutions (*i.e.,* mortgage companies or other non-bank creditors) subject to Regulation Z.[191]

Under the final rule, the Bureau generally accounts for the paperwork burden associated with Regulation Z for the following respondents pursuant to its administrative enforcement authority: insured depository institutions with more than $10 billion in total assets and their depository institution affiliates; privately insured credit unions; and certain nondepository creditors. The Bureau and the FTC generally both have enforcement authority over non-depository institutions for Regulation Z. Accordingly, the Bureau has allocated to itself half of the estimated burden to non-depository institutions. Other Federal agencies are responsible for estimating and reporting to OMB the total paperwork burden for the institutions for which they have administrative enforcement authority. They may, but are not required to, use the Bureau's burden estimation methodology.

Using the Bureau's burden estimation methodology, there is no change to the total estimated burden under Regulation Z as a result of the final rule.

[191] For purposes of this PRA analysis, references to ''creditors'' or ''lenders'' shall be deemed to refer collectively to commercial banks, savings institutions, credit unions, and mortgage companies (*i.e.,* non-depository lenders), unless otherwise stated. Moreover, reference to ''respondents'' shall generally mean all categories of entities identified in the sentence to which this footnote is appended, except as otherwise stated or if the context indicates otherwise.

B. Information Collection Requirements

Ability-to-Repay Verification and Documentation Requirements

As discussed above, the 2013 ATR Final Rule published in January 2013 contains specific criteria that a creditor must consider in assessing a consumer's repayment ability while different verification requirements apply to qualified mortgages. As described in the relevant sections of the final rule, the Bureau does not believe that the verification and documentation requirements of the final rule result in additional ongoing costs for most covered persons. However, for some creditors, notably the community-focused lending programs, housing finance agencies, and not-for profit organizations exempted in the final rule, lending can vary widely, in the form of financing, the products offered and the precise nature of underwriting. These processes may not involve the more traditional products covered by the qualified mortgage definition nor do these creditors use documentation and verification procedures closely aligned with the requirements of the 2013 ATR Final Rule.

For these creditors, the final rule should eliminate any costs from imposing these requirements on these particular extensions of credits. The Bureau estimates one-time and ongoing costs to respondents of complying with the final rule as follows.

One-time costs. The Bureau estimates that covered persons will incur one-time costs associated with reviewing the relevant sections of the **Federal Register** and training relevant employees. In general, the Bureau estimates these costs to include, for each covered person, the costs for one attorney and one compliance officer to read and review the sections of the final rule that describe the verification and documentation requirements for loans, the exemptions from the ability-to-repay requirements, and the costs for each loan officer or other loan originator to receive training concerning the requirements. However, the Bureau believes that respondents will review the relevant sections of this final rule along with the 2013 ATR Final Rule to best understand any new regulatory requirements and their coverage. As such, there is no additional one-time burden attributed to the final rule.

Ongoing costs. The exemptions for the covered institutions should reduce any burden related to these provisions. However, in the 2013 ATR Final Rule, the Bureau did not attribute any paperwork burden to these provisions on the assumption that the verification and documentation requirements of the 2013 ATR Final Rule will not result in additional ongoing costs for most covered persons. As such, it would be inappropriate to credit any reduction in burden to the final rule.

C. Summary of Burden Hours

As noted, the Bureau does not believe the final rule results in any changes in the burdens under Regulation Z associated with information collections for Bureau respondents under the PRA.

D. Comments

The Consumer Financial Protection Bureau has a continuing interest in the public's opinions of our collections of information. At any time, comments regarding the burden estimate, or any other aspect of this collection of information, including suggestions for reducing the burden, may be sent to:

The Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC, 20552, or by the internet to *CFPB_Public_PRA@cfpb.gov.*

List of Subjects in 12 CFR Part 1026

Advertising, Consumer protection, Mortgages, Reporting and recordkeeping requirements, Truth in Lending.

Authority and Issuance

For the reasons set forth in the preamble, the Bureau amends Regulation Z, 12 CFR part 1026, as amended by the final rules published on January 30, 2013 (78 FR 6408), and January 31, 2013 (78 FR 6962), as set forth below:

PART 1026—TRUTH IN LENDING (REGULATION Z)

■ 1. The authority citation for part 1026 continues to read as follows:

Authority: 12 U.S.C. 2601, 2603–2605, 2607, 2609, 2617, 5511, 5512, 5532, 5581; 15 U.S.C. 1601 *et seq.*

Subpart E—Special Rules for Certain Home Mortgage Transactions

■ 2. Section 1026.32 is amended by revising paragraphs (b)(1)(ii) and (b)(2)(ii) to read as follows:

§ 1026.32 Requirements for high-cost mortgages.

* * * * *

(b) * * *

(1) * * *

(ii) All compensation paid directly or indirectly by a consumer or creditor to a loan originator, as defined in § 1026.36(a)(1), that can be attributed to that transaction at the time the interest rate is set unless:

(A) That compensation is paid by a consumer to a mortgage broker, as defined in § 1026.36(a)(2), and already has been included in points and fees under paragraph (b)(1)(i) of this section;

(B) That compensation is paid by a mortgage broker, as defined in § 1026.36(a)(2), to a loan originator that is an employee of the mortgage broker; or

(C) That compensation is paid by a creditor to a loan originator that is an employee of the creditor.

* * * * *

(2) * * *

(ii) All compensation paid directly or indirectly by a consumer or creditor to a loan originator, as defined in § 1026.36(a)(1), that can be attributed to that transaction at the time the interest rate is set unless:

(A) That compensation is paid by a consumer to a mortgage broker, as defined in § 1026.36(a)(2), and already has been included in points and fees under paragraph (b)(2)(i) of this section;

(B) That compensation is paid by a mortgage broker, as defined in § 1026.36(a)(2), to a loan originator that is an employee of the mortgage broker; or

(C) That compensation is paid by a creditor to a loan originator that is an employee of the creditor.

* * * * *

■ 3. Section 1026.43 is amended by revising paragraphs (a)(3)(ii) and (iii), (b)(4), (e)(1), (e)(2), and (g)(1)(ii)(B), and adding new paragraphs (a)(3)(iv) through (vi), (e)(5) and (e)(6), to read as follows:

§ 1026.43 Minimum standards for transactions secured by a dwelling.

(a) * * *

(3) * * *

(ii) A temporary or ''bridge'' loan with a term of 12 months or less, such as a loan to finance the purchase of a new dwelling where the consumer plans to sell a current dwelling within 12 months or a loan to finance the initial construction of a dwelling;

(iii) A construction phase of 12 months or less of a construction-to-permanent loan;

(iv) An extension of credit made pursuant to a program administered by a Housing Finance Agency, as defined under 24 CFR 266.5;

(v) An extension of credit made by:

(A) A creditor designated as a Community Development Financial Institution, as defined under 12 CFR 1805.104(h);

(B) A creditor designated as a Downpayment Assistance through Secondary Financing Provider, pursuant

to 24 CFR 200.194(a), operating in accordance with regulations prescribed by the U.S. Department of Housing and Urban Development applicable to such persons;

(C) A creditor designated as a Community Housing Development Organization provided that the creditor has entered into a commitment with a participating jurisdiction and is undertaking a project under the HOME program, pursuant to the provisions of 24 CFR 92.300(a), and as the terms community housing development organization, commitment, participating jurisdiction, and project are defined under 24 CFR 92.2; or

(D) A creditor with a tax exemption ruling or determination letter from the Internal Revenue Service under section 501(c)(3) of the Internal Revenue Code of 1986 (26 U.S.C. 501(c)(3); 26 CFR 1.501(c)(3)–1), provided that:

(*1*) During the calendar year preceding receipt of the consumer's application, the creditor extended credit secured by a dwelling no more than 200 times;

(*2*) During the calendar year preceding receipt of the consumer's application, the creditor extended credit secured by a dwelling only to consumers with income that did not exceed the low- and moderate-income household limit as established pursuant to section 102 of the Housing and Community Development Act of 1974 (42 U.S.C. 5302(a)(20)) and amended from time to time by the U.S. Department of Housing and Urban Development, pursuant to 24 CFR 570.3;

(*3*) The extension of credit is to a consumer with income that does not exceed the household limit specified in paragraph (a)(3)(v)(D)(*2*) of this section; and

(*4*) The creditor determines, in accordance with written procedures, that the consumer has a reasonable ability to repay the extension of credit.

(vi) An extension of credit made pursuant to a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008 (12 U.S.C. 5211; 5219);

(b) * * *

(4) *Higher-priced covered transaction* means a covered transaction with an annual percentage rate that exceeds the average prime offer rate for a comparable transaction as of the date the interest rate is set by 1.5 or more percentage points for a first-lien covered transaction, other than a qualified mortgage under paragraph (e)(5), (e)(6), or (f) of this section; by 3.5 or more percentage points for a first-lien covered transaction that is a qualified mortgage under paragraph (e)(5), (e)(6), or (f) of this section; or by 3.5 or more percentage points for a subordinate-lien covered transaction.

* * * * *

(e) *Qualified mortgages.* (1) *Safe harbor and presumption of compliance.* (i) *Safe harbor for loans that are not higher-priced covered transactions.* A creditor or assignee of a qualified mortgage, as defined in paragraphs (e)(2), (e)(4), (e)(5), (e)(6), or (f) of this section, that is not a higher-priced covered transaction, as defined in paragraph (b)(4) of this section, complies with the repayment ability requirements of paragraph (c) of this section.

(ii) *Presumption of compliance for higher-priced covered transactions.* (A) A creditor or assignee of a qualified mortgage, as defined in paragraph (e)(2), (e)(4), (e)(5), (e)(6), or (f) of this section, that is a higher-priced covered transaction, as defined in paragraph (b)(4) of this section, is presumed to comply with the repayment ability requirements of paragraph (c) of this section.

(B) To rebut the presumption of compliance described in paragraph (e)(1)(ii)(A) of this section, it must be proven that, despite meeting the prerequisites of paragraph (e)(2), (e)(4), (e)(5), (e)(6), or (f) of this section, the creditor did not make a reasonable and good faith determination of the consumer's repayment ability at the time of consummation, by showing that the consumer's income, debt obligations, alimony, child support, and the consumer's monthly payment (including mortgage-related obligations) on the covered transaction and on any simultaneous loans of which the creditor was aware at consummation would leave the consumer with insufficient residual income or assets other than the value of the dwelling (including any real property attached to the dwelling) that secures the loan with which to meet living expenses, including any recurring and material non-debt obligations of which the creditor was aware at the time of consummation.

(2) *Qualified mortgage defined—general.* Except as provided in paragraph (e)(4), (e)(5), (e)(6), or (f) of this section, a qualified mortgage is a covered transaction:

* * * * *

(5) *Qualified mortgage defined—small creditor portfolio loans.* (i) Notwithstanding paragraph (e)(2) of this section, a qualified mortgage is a covered transaction:

(A) That satisfies the requirements of paragraph (e)(2) of this section other than the requirements of paragraph (e)(2)(vi) and without regard to the standards in appendix Q to this part;

(B) For which the creditor considers at or before consummation the consumer's monthly debt-to-income ratio or residual income and verifies the debt obligations and income used to determine that ratio in accordance with paragraph (c)(7) of this section, except that the calculation of the payment on the covered transaction for purposes of determining the consumer's total monthly debt obligations in paragraph (c)(7)(i)(A) shall be determined in accordance with paragraph (e)(2)(iv) of this section instead of paragraph (c)(5) of this section;

(C) That is not subject, at consummation, to a commitment to be acquired by another person, other than a person that satisfies the requirements of paragraph (e)(5)(i)(D) of this section; and

(D) For which the creditor satisfies the requirements stated in § 1026.35(b)(2)(iii)(B) and (C).

(ii) A qualified mortgage extended pursuant to paragraph (e)(5)(i) of this section immediately loses its status as a qualified mortgage under paragraph (e)(5)(i) if legal title to the qualified mortgage is sold, assigned, or otherwise transferred to another person except when:

(A) The qualified mortgage is sold, assigned, or otherwise transferred to another person three years or more after consummation of the qualified mortgage;

(B) The qualified mortgage is sold, assigned, or otherwise transferred to a creditor that satisfies the requirements of paragraph (e)(5)(i)(D) of this section;

(C) The qualified mortgage is sold, assigned, or otherwise transferred to another person pursuant to a capital restoration plan or other action under 12 U.S.C. 1831o, actions or instructions of any person acting as conservator, receiver, or bankruptcy trustee, an order of a State or Federal government agency with jurisdiction to examine the creditor pursuant to State or Federal law, or an agreement between the creditor and such an agency; or

(D) The qualified mortgage is sold, assigned, or otherwise transferred pursuant to a merger of the creditor with another person or acquisition of the creditor by another person or of another person by the creditor.

(6) *Qualified mortgage defined—temporary balloon-payment qualified mortgage rules.* (i) Notwithstanding paragraph (e)(2) of this section, a qualified mortgage is a covered transaction:

(A) That satisfies the requirements of paragraph (f) of this section other than

the requirements of paragraph (f)(1)(vi); and

(B) For which the creditor satisfies the requirements stated in § 1026.35(b)(2)(iii)(B) and (C).

(ii) The provisions of this paragraph (e)(6) apply only to covered transactions consummated on or before January 10, 2016.

* * * * *

(g) * * *

(1) * * *

(ii) * * *

(B) Is a qualified mortgage under paragraph (e)(2), (e)(4), (e)(5), (e)(6), or (f) of this section; and

* * * * *

■ 4. In Supplement I to Part 1026—Official Interpretations:

■ A. Under *Section 1026.32—Requirements for High-Cost Mortgages:*

■ i. Under *32(b) Definitions:*

■ a. Under *Paragraph 32(b)(1)(ii),* paragraphs 1, 2, 3, and 4 are revised.

■ B. Under *Section 1026.43—Minimum Standards for Transactions Secured by a Dwelling:*

■ i. Under *43(a) Scope:*

■ a. *Paragraph 43(a)(3)(iv)* and paragraph 1 are added.

■ b. *Paragraph 43(a)(3)(v)(D)* and paragraph 1 are added.

■ c. *Paragraph 43(a)(3)(vi)* and paragraph 1 are added.

■ ii. Under *43(e) Qualified Mortgages:*

■ a. *Paragraph 43(e)(5)* and paragraphs 1 through 10 are added.

The revisions and additions read as follows:

Supplement I to Part 1026—Official Interpretations

* * * * *

Subpart E—Special Rules for Certain Home Mortgage Transactions

* * * * *

Section 1026.32—Requirements for High-Cost Mortgages

* * * * *

32(b) Definitions.

* * * * *

Paragraph 32(b)(1)(ii).

1. *Loan originator compensation—general.* Compensation paid by a consumer or creditor to a loan originator, other than an employee of the creditor, is included in the calculation of points and fees for a transaction, provided that such compensation can be attributed to that particular transaction at the time the interest rate is set. Compensation paid to an employee of a creditor is not included in points and fees. Loan originator compensation includes amounts the loan originator retains and is not dependent on the label or name of any fee imposed in connection with the transaction.

2. *Loan originator compensation—attributable to a particular transaction.* Loan originator compensation is compensation that is paid by a consumer or creditor to a loan originator that can be attributed to that particular transaction. The amount of compensation that can be attributed to a particular transaction is the dollar value of compensation that the loan originator will receive if the transaction is consummated. As explained in comment 32(b)(1)(ii)–3, the amount of compensation that a loan originator will receive is calculated as of the date the interest rate is set and includes compensation that is paid before, at, or after consummation.

3. *Loan originator compensation—timing.* Compensation paid to a loan originator that can be attributed to a transaction must be included in the points and fees calculation for that loan regardless of whether the compensation is paid before, at, or after consummation. The amount of loan originator compensation that can be attributed to a transaction is determined as of the date the interest rate is set. Thus, loan originator compensation for a transaction includes compensation that can be attributed to that transaction at the time the creditor sets the interest rate for the transaction, even if that compensation is not paid until after consummation.

4. *Loan originator compensation—calculating loan originator compensation in connection with other charges or payments included in the finance charge or made to loan originators.* i. *Consumer payments to mortgage brokers.* As provided in § 1026.32(b)(1)(ii)(A), consumer payments to a mortgage broker already included in the points and fees calculation under § 1026.32(b)(1)(i) need not be counted again under § 1026.32(b)(1)(ii). For example, assume a consumer pays a mortgage broker a $3,000 fee for a transaction. The $3,000 mortgage broker fee is included in the finance charge under § 1026.4(a)(3). Because the $3,000 mortgage broker fee is already included in points and fees under § 1026.32(b)(1)(i), it is not counted again under § 1026.32(b)(1)(ii).

ii. *Payments by a mortgage broker to its individual loan originator employee.* As provided in § 1026.32(b)(1)(ii)(B), compensation paid by a mortgage broker to its individual loan originator employee is not included in points and fees under § 1026.32(b)(1)(ii). For example, assume a consumer pays a $3,000 fee to a mortgage broker, and the mortgage broker pays a $1,500 commission to its individual loan originator employee for that transaction. The $3,000 mortgage broker fee is included in points and fees, but the $1,500 commission is not included in points and fees because it has already been included in points and fees as part of the $3,000 mortgage broker fee.

iii. *Creditor's origination fees—loan originator not employed by creditor.* Compensation paid by a consumer or creditor to a loan originator who is not employed by the creditor is included in the calculation of points and fees under § 1026.32(b)(1)(ii). Such compensation is included in points and fees in addition to any origination fees or charges paid by the consumer to the creditor that are included in points and fees under § 1026.32(b)(1)(i). For example, assume that a consumer pays to the creditor a $3,000 origination fee and that the creditor pays a mortgage broker $1,500 in compensation attributed to the transaction. Assume further that the consumer pays no other charges to the creditor that are included in points and fees under § 1026.32(b)(1)(i) and that the mortgage broker receives no other compensation that is included in points and fees under § 1026.32(b)(1)(ii). For purposes of calculating points and fees, the $3,000 origination fee is included in points and fees under § 1026.32(b)(1)(i) and the $1,500 in loan originator compensation is included in points and fees under § 1026.32(b)(1)(ii), equaling $4,500 in total points and fees, provided that no other points and fees are paid or compensation received.

* * * * *

Section 1026.43—Minimum Standards for Transactions Secured by a Dwelling

43(a) Scope.

* * * * *

Paragraph 43(a)(3)(iv).

1. *General.* The requirements of § 1026.43(c) through (f) do not apply to an extension of credit made pursuant to a program administered by a Housing Finance Agency, as defined under 24 CFR 266.5. Under the exemption, the requirements of § 1026.43(c) through (f) do not apply to extensions of credit made by housing finance agencies and extensions of credit made by intermediaries (*e.g.,* private creditors) pursuant to a program administered by a housing finance agency. For example, if a creditor is extending credit, including a subordinate-lien covered transaction, that will be made pursuant to a program administered by a housing finance agency, the creditor is exempt from the requirements of § 1026.43(c) through (f). Similarly, the creditor is exempt from the requirements of § 1026.43(c) through (f) regardless of whether the program administered by a housing finance agency is funded by Federal, State, or other sources.

Paragraph 43(a)(3)(v)(D).

1. *General.* An extension of credit is exempt from the requirements of § 1026.43(c) through (f) if the credit is extended by a creditor described in § 1026.43(a)(3)(v)(D), provided the conditions specified in that section are satisfied. The conditions specified in § 1026.43(a)(3)(v)(D)(*1*) and (*2*) are determined according to activity that occurred in the calendar year preceding the calendar year in which the consumer's application was received. Section 1026.43(a)(3)(v)(D)(*2*) provides that, during the preceding calendar year, the creditor must have extended credit only to consumers with income that did not exceed the limit then in effect for low- and moderate-income households, as specified in regulations prescribed by the U.S. Department of Housing and Urban Development pursuant to 24 CFR 570.3. For example, a creditor has satisfied the requirement in § 1026.43(a)(3)(v)(D)(*2*) if the creditor extended credit only to consumers with incomes that did not exceed the limit in effect on the dates the creditor received each consumer's individual application. The condition specified in § 1026.43(a)(3)(v)(D)(*3*), which relates to the

current extension of credit, provides that the extension of credit must be to a consumer with income that does not exceed the limit specified in § 1026.43(a)(3)(v)(D)(*2*) in effect on the date the creditor received the consumer's application. For example, assume that a creditor with a tax exemption ruling under section 501(c)(3) of the Internal Revenue Code of 1986 has satisfied the conditions identified in § 1026.43(a)(3)(v)(D)(*1*) and (*2*). If, on May 21, 2014, the creditor in this example extends credit secured by a dwelling to a consumer whose application reflected income in excess of the limit identified in § 1026.43(a)(3)(v)(D)(*2*) in effect on the date the creditor received that consumer's application, the creditor has not satisfied the condition in § 1026.43(a)(3)(v)(D)(*3*) and this extension of credit is not exempt from the requirements of § 1026.43(c) through (f).

Paragraph 43(a)(3)(vi).

1. *General.* The requirements of § 1026.43(c) through (f) do not apply to a mortgage loan modification made in connection with a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008. If a creditor is underwriting an extension of credit that is a refinancing, as defined by § 1026.20(a), that will be made pursuant to a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008, the creditor also need not comply with § 1026.43(c) through (f). A creditor need not determine whether the mortgage loan modification is considered a refinancing under § 1026.20(a) for purposes of determining applicability of § 1026.43; if the transaction is made in connection with these programs, the requirements of § 1026.43(c) through (f) do not apply. In addition, if a creditor underwrites a new extension of credit, such as a subordinate-lien mortgage loan, that will be made pursuant to a program authorized by sections 101 and 109 of the Emergency Economic Stabilization Act of 2008, the creditor need not comply with the requirements of § 1026.43(c) through (f).

* * * * *

43(e) Qualified mortgages.

* * * * *

Paragraph 43(e)(5).

1. *Satisfaction of qualified mortgage requirements.* For a covered transaction to be a qualified mortgage under § 1026.43(e)(5), the mortgage must satisfy the requirements for a qualified mortgage under § 1026.43(e)(2), other than the requirements regarding debt-to-income ratio. For example, a qualified mortgage under § 1026.43(e)(5) may not have a loan term in excess of 30 years because longer terms are prohibited for qualified mortgages under § 1026.43(e)(2)(ii). Similarly, a qualified mortgage under § 1026.43(e)(5) may not result in a balloon payment because § 1026.43(e)(2)(i)(C) provides that qualified mortgages may not have balloon payments except as provided under § 1026.43(f). However, a covered transaction need not comply with § 1026.43(e)(2)(vi), which prohibits consumer monthly debt-to-income ratios in excess of 43 percent. A covered transaction therefore can be a qualified mortgage under § 1026.43(e)(5) even though the consumer's monthly debt-to-income ratio is greater than 43 percent.

2. *Debt-to-income ratio or residual income.* Section 1026.43(e)(5) does not prescribe a specific monthly debt-to-income ratio with which creditors must comply. Instead, creditors must consider a consumer's debt-to-income ratio or residual income calculated generally in accordance with § 1026.43(c)(7) and verify the information used to calculate the debt-to-income ratio or residual income in accordance with § 1026.43(c)(3) and (4). However, § 1026.43(c)(7) refers creditors to § 1026.43(c)(5) for instructions on calculating the payment on the covered transaction. Section 1026.43(c)(5) requires creditors to calculate the payment differently than § 1026.43(e)(2)(iv). For purposes of the qualified mortgage definition in § 1026.43(e)(5), creditors must base their calculation of the consumer's debt-to-income ratio or residual income on the payment on the covered transaction calculated according to § 1026.43(e)(2)(iv) instead of according to § 1026.43(c)(5). Creditors are not required to calculate the consumer's monthly debt-to-income ratio in accordance with appendix Q to this part as is required under the general definition of qualified mortgages by § 1026.43(e)(2)(vi).

3. *Forward commitments.* A creditor may make a mortgage loan that will be transferred or sold to a purchaser pursuant to an agreement that has been entered into at or before the time the transaction is consummated. Such an agreement is sometimes known as a ''forward commitment.'' A mortgage that will be acquired by a purchaser pursuant to a forward commitment does not satisfy the requirements of § 1026.43(e)(5), whether the forward commitment provides for the purchase and sale of the specific transaction or for the purchase and sale of transactions with certain prescribed criteria that the transaction meets. However, a forward commitment to another person that also meets the requirements of § 1026.43(e)(5)(i)(D) is permitted. For example, assume a creditor that is eligible to make qualified mortgages under § 1026.43(e)(5) makes a mortgage. If that mortgage meets the purchase criteria of an investor with which the creditor has an agreement to sell loans after consummation, then the loan does not meet the definition of a qualified mortgage under § 1026.43(e)(5). However, if the investor meets the requirements of § 1026.43(e)(5)(i)(D), the mortgage will be a qualified mortgage if all other applicable criteria also are satisfied.

4. *Creditor qualifications.* To be eligible to make qualified mortgages under § 1026.43(e)(5), a creditor must satisfy the requirements stated in § 1026.35(b)(2)(iii)(B) and (C). Section 1026.35(b)(2)(iii)(B) requires that, during the preceding calendar year, the creditor and its affiliates together originated 500 or fewer first-lien covered transactions. Section 1026.35(b)(2)(iii)(C) requires that, as of the end of the preceding calendar year, the creditor had total assets of less than $2 billion, adjusted annually by the Bureau for inflation.

5. *Requirement to hold in portfolio.* Creditors generally must hold a loan in portfolio to maintain the transaction's status as a qualified mortgage under § 1026.43(e)(5), subject to four exceptions. Unless one of these exceptions applies, a loan is no longer a qualified mortgage under § 1026.43(e)(5) once legal title to the debt obligation is sold, assigned, or otherwise transferred to another person. Accordingly, unless one of the exceptions applies, the transferee could not benefit from the presumption of compliance for qualified mortgages under § 1026.43(e)(1) unless the loan also met the requirements of another qualified mortgage definition.

6. *Application to subsequent transferees.* The exceptions contained in § 1026.43(e)(5)(ii) apply not only to an initial sale, assignment, or other transfer by the originating creditor but to subsequent sales, assignments, and other transfers as well. For example, assume Creditor A originates a qualified mortgage under § 1026.43(e)(5). Six months after consummation, Creditor A sells the qualified mortgage to Creditor B pursuant to § 1026.43(e)(5)(ii)(B) and the loan retains its qualified mortgage status because Creditor B complies with the limits on asset size and number of transactions. If Creditor B sells the qualified mortgage, it will lose its qualified mortgage status under § 1026.43(e)(5) unless the sale qualifies for one of the § 1026.43(e)(5)(ii) exceptions for sales three or more years after consummation, to another qualifying institution, as required by supervisory action, or pursuant to a merger or acquisition.

7. *Transfer three years after consummation.* Under § 1026.43(e)(5)(ii)(A), if a qualified mortgage under § 1026.43(e)(5) is sold, assigned, or otherwise transferred three years or more after consummation, the loan retains its status as a qualified mortgage under § 1026.43(e)(5) following the transfer. The transferee need not be eligible to originate qualified mortgages under § 1026.43(e)(5). The loan will continue to be a qualified mortgage throughout its life, and the transferee, and any subsequent transferees, may invoke the presumption of compliance for qualified mortgages under § 1026.43(e)(1).

8. *Transfer to another qualifying creditor.* Under § 1026.43(e)(5)(ii)(B), a qualified mortgage under § 1026.43(e)(5) may be sold, assigned, or otherwise transferred at any time to another creditor that meets the requirements of § 1026.43(e)(5)(v). That section requires that a creditor, during the preceding calendar year, together with all affiliates, 500 or fewer first-lien covered transactions and had total assets less than $2 billion (as adjusted for inflation) at the end of the preceding calendar year. A qualified mortgage under § 1026.43(e)(5) transferred to a creditor that meets these criteria would retain its qualified mortgage status even if it is transferred less than three years after consummation.

9. *Supervisory sales.* Section 1026.43(e)(5)(ii)(C) facilitates sales that are deemed necessary by supervisory agencies to revive troubled creditors and resolve failed creditors. A qualified mortgage under § 1026.43(e)(5) retains its qualified mortgage status if it is sold, assigned, or otherwise transferred to another person pursuant to: A capital restoration plan or other action under

12 U.S.C. 1831o; the actions or instructions of any person acting as conservator, receiver or bankruptcy trustee; an order of a State or Federal government agency with jurisdiction to examine the creditor pursuant to State or Federal law; or an agreement between the creditor and such an agency. A qualified mortgage under § 1026.43(e)(5) that is sold, assigned, or otherwise transferred under these circumstances retains its qualified mortgage status regardless of how long after consummation it is sold and regardless of the size or other characteristics of the transferee. Section 1026.43(e)(5)(ii)(C) does not apply to transfers done to comply with a generally applicable regulation with future effect designed to implement, interpret, or prescribe law or policy in the absence of a specific order by or a specific agreement with a governmental agency described in § 1026.43(e)(5)(ii)(C) directing the sale of one or more qualified mortgages under § 1026.43(e)(5) held by the creditor or one of the other circumstances listed in § 1026.43(e)(5)(ii)(C). For example, a qualified mortgage under § 1026.43(e)(5) that is sold pursuant to a capital restoration plan under 12 U.S.C. 1831o would retain its status as a qualified mortgage following the sale. However, if the creditor simply chose to sell the same qualified mortgage as one way to comply with general regulatory capital requirements in the absence of supervisory action or agreement it would lose its status as a qualified mortgage following the sale unless it qualifies under another definition of qualified mortgage.

10. *Mergers and acquisitions.* A qualified mortgage under § 1026.43(e)(5) retains its qualified mortgage status if a creditor merges with, is acquired by, or acquires another person regardless of whether the creditor or its successor is eligible to originate new qualified mortgages under § 1026.43(e)(5) after the merger or acquisition. However, the creditor or its successor can originate new qualified mortgages under § 1026.43(e)(5) only if it complies with all of the requirements of § 1026.43(e)(5) after the merger or acquisition. For example, assume a creditor that originates 250 covered transactions each year and originates qualified mortgages under § 1026.43(e)(5) is acquired by a larger creditor that originates 10,000 covered transactions each year. Following the acquisition, the small creditor would no longer be able to originate § 1026.43(e)(5) qualified mortgages because, together with its affiliates, it would originate more than 500 covered transactions each year. However, the § 1026.43(e)(5) qualified mortgages originated by the small creditor before the acquisition would retain their qualified mortgage status.

* * * * *

Dated: May 29, 2013.

Richard Cordray,

Director, Bureau of Consumer Financial Protection.

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Part IV

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National Oceanic and Atmospheric Administration

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Seismic Survey in the Chukchi Sea, Alaska; Notice

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC563

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Marine Seismic Survey in the Chukchi Sea, Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS received an application from TGS–NOPEC Geophysical Company ASA (TGS) for an Incidental Harassment Authorization (IHA) to take marine mammals, by harassment only, incidental to a marine 2-dimensional (2D) seismic survey program in the Chukchi Sea, Alaska, during the open water season of 2013. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to TGS to take, by Level B harassment, 12 species of marine mammals during the specified activity.

DATES: Comments and information must be received no later than July 12, 2013.

ADDRESSES: Comments on the application should be addressed to P. Michael Payne, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing email comments is *ITP.guan@noaa.gov.* NMFS is not responsible for email comments sent to addresses other than the one provided here. Comments sent via email, including all attachments, must not exceed a 10-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications* without change. All Personal Identifying Information (for example, name, address, etc.) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

The application used in this document may be obtained by visiting the internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications.* Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Shane Guan, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:

Background

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

Authorization for incidental takings shall be granted if NMFS finds that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''...an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.''

Section 101(a)(5)(D) of the MMPA established an expedited process by which citizens of the U.S. can apply for an authorization to incidentally take small numbers of marine mammals by harassment. Section 101(a)(5)(D) establishes a 45-day time limit for NMFS review of an application followed by a 30-day public notice and comment period on any proposed authorizations for the incidental harassment of marine mammals. Within 45 days of the close of the comment period, NMFS must either issue or deny the authorization.

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [''Level A harassment'']; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [''Level B harassment'']].

Summary of Request

On December 3, 2012, NMFS received an application from TGS requesting an authorization for the harassment of small numbers of marine mammals incidental to conducting an open-water 2D seismic survey in the Chukchi Sea off Alaska. After addressing comments from NMFS, TGS modified its application and submitted a revised application on April 1, 2013, and a revised marine mammal monitoring and mitigation plan on April 15, 2013, with additional clarification on May 7, 2013. TGS' proposed activities discussed here are based on its April 1, 2013, IHA application and April 15, 2013, marine mammal monitoring and mitigation measures.

Description of the Specified Activity

TGS proposes to conduct approximately 9,600 km of marine 2D seismic surveys along pre-determined lines in U.S. waters and international waters of the Chukchi Sea (Figure 1 of TGS' IHA application) during the 2013 open water season. The purpose of the proposed seismic program is to gather geophysical data using a 3,280 in^3 seismic source array and an 8,100-m long hydrophone solid streamer towed by the seismic vessel. Results of the 2D seismic program would be used to identify and map potential hydrocarbon-bearing formations and the geologic structures that surround them.

TGS plans to enter the U.S. Chukchi Sea sometime between 15 July and 5 August, 2013. Approximately 35 days of seismic operations are expected to occur over a period of about 45–60 days in U.S. Chukchi Sea. In addition, up to 33 days of seismic operations may occur in international waters (depending on ice and weather conditions). Seismic operations are proposed to occur along pre-determined track lines at speeds of about four to five knots. Seismic operations would be conducted up to 24 hours per day as possible except as potentially needed for shut-down mitigation for marine mammals. The full 3,280 in^3 airgun array would only be firing during seismic acquisition operations on and near the end and start of survey lines; during turns and transits between seismic lines, a single ''mitigation'' airgun (60 in^3 or smaller) is proposed to be operated.

Two vessels would be used during the survey: (1) A seismic operations vessel that would tow the seismic source array hydrophone solid streamer, and (2) a smaller vessel that will be used to search for marine mammals and scout

for ice and other navigation hazards ahead of the seismic vessel. In the event of an emergency, the scout vessel may be used to support the seismic vessel. In this extraordinary circumstance, all seismic activity will cease since the scout vessel will no longer be devoted to monitoring the exclusion zones.

The seismic vessel will tow a compressed-air seismic source array of 28 Bolt 1900 LLXT airguns with a total discharge volume of 3,280 in^3. The airguns range in volume from 40 in^3 to 300 in^3 and are arranged in a geometric lay-out of three sub-arrays that will be towed approximately 200 m behind the vessel at a depth of 6 m. The seismic source would discharge every 25 m (82 ft) or approximately every 10 seconds. Additional details regarding seismic acquisition parameters are provided in TGS' IHA application. To ascertain whether the seismic source array is operating correctly, the full volume will be enabled for 1 km from the start of every line (i.e., a run in). To ensure full fold data acquisition the vessel will require a 4 km run out at the conclusion of each line. TGS states that gravity and magnetic data will also be passively acquired during the survey by measuring gravity and magnetic variations while traversing the lines (no acoustics are involved with these methods).

The acoustic source level of the proposed 3,280 in^3 seismic source array was predicted using JASCO's airgun array source model (AASM) based on data collected from three sites chosen in the project area by JASCO. Water depths at the three sites were 17, 40, and 100 m. JASCO applied its Marine Operations Noise Model (MONM) to estimate acoustic propagation of the proposed seismic source array and the associated distances to the 190, 180 and 160 dB (rms) re 1 μPa isopleths. The resulting isopleths modeled for the 180 and 190 dB (rms) re 1 μPa exclusion zone distances for cetaceans and pinnipeds, respectively, differed with the three water depths. An additional 10 percent distance buffer was added by JASCO to these originally modeled distances to provide larger, more protective exclusion zone radii distances that will be adhered to during the project (Table 1).

The estimated distances to the 190, 180 and 160 dB re 1μPa (rms) isopleths for the single 60 in3 airgun (the largest single airgun that would be used as a ''mitigation'' gun) were measured by JASCO during a monitoring sound source verification (SSV) study conducted for Statoil in 2010 in the Chukchi Sea during the open water season of 2010 (Blees *et al.* 2010). Results indicated that the distance to the 190 dB isopleth was 13 m, the 180 dB isopleth distance was 68 m, and the 160 dB isopleth distance was 1,500 m (all dB (rms) re 1 μPa).

TABLE 1—MODELED DISTANCES IN (METERS) TO RECEIVED SOUND LEVELS FOR THE TGS' 3,280 IN^3 AIRGUN ARRAY IN WATERS WITH THREE DIFFERENT DEPTHS IN THE CHUKCHI SEA

Water depths (m)	Received sound level (dB re 1 μPa rms)		
	190	180	160
17–40	930	2,200	8,500
40–100	920	2,500	9,900
>100	430	2,400	15,000

Both vessels would use industry-standard echosounder/fathometer instruments to continuously monitor water depth for navigation purposes while underway. These instruments are the same as those used aboard all large vessels to obtain information on water depths and potential navigation hazards for vessel crews during routine navigation operations. Navigation echosounders direct a single, high-frequency acoustic signal that is focused in a narrow beam directly downward to the sea floor. The reflected sound energy is detected by the echosounder instrument which then calculates and displays water depth to the user. Typical source levels of these types of navigational echosounders are generally 180–200 dB re 1 μPa at 1 m.

One navigational echosounder would be used by the seismic vessel and another one will be used by the scout vessel. The echosounder used by the seismic vessel will consist of a downward-facing single-beam (Kongsberg EA600) that operates at frequencies of 18 to 200 kHz (output power 1–2 kilowatt [kW]). Associated pulse durations are 0.064 and 4.096 milliseconds (ms) long and repetition frequency of the pulse (i.e., the ping rate) is related to water depth. In shallow water, the highest pulse repetition frequency is about 20 pings per second. The scout vessel will use a Furuno 292 echosounder that operates at a frequency of 28 and 88 kHz. The highest ping rate in shallow water is 12 pings per second.

Dates, Duration and Action Area

As stated earlier, TGS plans to enter the U.S. Chukchi as early as July 15, 2013, and conduct its proposed 2D seismic surveys in both the U.S. Chukchi Sea and international waters through October 31, 2013. Seismic operations are anticipated to occur for about 35 days over a period of 45–60 days in U.S. waters and up to about 33 days in international waters. Operations in U.S. waters are expected to be complete no later than 5 October 2013. However, poor weather, ice conditions, equipment repair, etc., would likely delay or curtail operations. Thus, this extended period allows flexibility in proposed operational dates, contingent on such conditions. Specific proposed dates and durations of project activities are listed below in chronological order, but are contingent on weather and ice, etc.

The seismic operations are proposed to occur in U.S. and international waters of the Chukchi Sea between about 70–77° N and 154–165° W (Figure 1 of TGS' IHA application). Up to approximately 6,088 km of seismic operations with the full sound source are planned to be conducted in U.S. waters as follows, which include 5,973 km of pre-plot lines plus approximately 115 km for 1-km run-in and 5-km run-out between seismic lines. In addition, approximately 1,556 km with the single 60 in^3 (or smaller) mitigation airgun are planned to be conducted during turns and transits between lines. Approximately 3,691 km of seismic operations with the full seismic source as follows are planned to be conducted in international waters, which include 3,631 km of pre-plot lines plus about 60 km of 1-km run-in and 5-km run-out between pre-plot lines. In addition, approximately 812 km with the single 60 in3 (or smaller) mitigation airgun are planned to be conducted during turns and transits between seismic lines. Most of the total approximately 9,600 km of proposed seismic lines occur in water 40–100 m deep (82% or 7,890 km), followed by waters >100 m deep (14% or 1,320 km) and waters <40 m deep (4% or 390 km).

Description of Marine Mammals in the Area of the Specified Activity

The marine mammal species under NMFS jurisdiction most likely to occur in the seismic survey area include eight cetacean species: beluga whale (*Delphinapterus leucas*), harbor porpoise (*Phocoena phocoena*), killer whale (*Orcinus orca*), bowhead whale (*Balaena mysticetus*), gray whale (*Eschrichtius robustus*), minke whale (*Balaenoptera acutorostrata*), fin whale (*B. physalus*), and humpback whale (*Megaptera novaeangliae*), and four pinniped species, ringed (*Phoca hispida*), spotted (*P. largha*), bearded (*Erignathus barbatus*), and ribbon seals (*Histriophoca fasciata*).

The bowhead, fin, and humpback whales are listed as ''endangered'', and the ringed and bearded seals are listed as ''threatened'' under the Endangered Species Act (ESA) and as depleted under the MMPA. Certain stocks or populations of gray and beluga whales and spotted seals are also listed under the ESA, however, none of those stocks or populations occur in the proposed activity area.

TGS' application contains information on the status, distribution, seasonal distribution, and abundance of each of the species under NMFS jurisdiction mentioned in this document. Please refer to the application for that information (see **ADDRESSES**). Additional information can also be found in the NMFS Stock Assessment Reports (SAR). The Alaska 2012 SAR is available at: *http://www.nmfs.noaa.gov/pr/sars/pdf/ak2012.pdf.*

Potential Effects of the Specified Activity on Marine Mammals

Operating active acoustic sources such as airgun arrays, navigational sonars, and vessel activities has the potential for adverse effects on marine mammals.

Potential Effects of Airgun Sounds on Marine Mammals

The effects of sounds from airgun pulses might include one or more of the following: tolerance, masking of natural sounds, behavioral disturbance, and temporary or permanent hearing impairment or non-auditory effects (Richardson *et al.* 1995). As outlined in previous NMFS documents, the effects of noise on marine mammals are highly variable, and can be categorized as follows (based on Richardson *et al.* 1995):

(1) Behavioral Disturbance

Marine mammals may behaviorally react to sound when exposed to anthropogenic noise. These behavioral reactions are often shown as: changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where noise sources are located; and/or flight responses (e.g., pinnipeds flushing into water from haulouts or rookeries).

The biological significance of many of these behavioral disturbances is difficult to predict, especially if the detected disturbances appear minor. However, the consequences of behavioral modification could be expected to be biologically significant if the change affects growth, survival, and reproduction. Some of these potential significant behavioral modifications include:

- Drastic change in diving/surfacing patterns (such as those thought to be causing beaked whale stranding due to exposure to military mid-frequency tactical sonar);
- Habitat abandonment due to loss of desirable acoustic environment; and
- Cease feeding or social interaction.

For example, at the Guerreo Negro Lagoon in Baja California, Mexico, which is one of the important breeding grounds for Pacific gray whales, shipping and dredging associated with a salt works may have induced gray whales to abandon the area through most of the 1960s (Bryant *et al.* 1984). After these activities stopped, the lagoon was reoccupied, first by single whales and later by cow-calf pairs.

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography) and is also difficult to predict (Southall *et al.* 2007).

Currently NMFS uses 160 dB re 1 μPa (rms) at received level for impulse noises (such as airgun pulses) as the threshold for the onset of marine mammal behavioral harassment.

In addition, behavioral disturbance is also expressed as the change in vocal activities of animals. For example, there is one recent summary report indicating that calling fin whales distributed in one part of the North Atlantic went silent for an extended period starting soon after the onset of a seismic survey in the area (Clark and Gagnon 2006). It is not clear from that preliminary paper whether the whales ceased calling because of masking, or whether this was a behavioral response not directly involving masking (i.e., important biological signals for marine mammals being ''masked'' by anthropogenic noise; see below). Also, bowhead whales in the Beaufort Sea may decrease their call rates in response to seismic operations, although movement out of the area might also have contributed to the lower call detection rate (Blackwell *et al.* 2009a; 2009b). Some of the changes in marine mammal vocal communication are thought to be used to compensate for acoustic masking resulting from increased anthropogenic noise (see below). For example, blue whales are found to increase call rates when exposed to seismic survey noise in the St. Lawrence Estuary (Di Iorio and Clark 2009). The North Atlantic right whales (*Eubalaena glacialis*) exposed to high shipping noise increase call frequency (Parks *et al.* 2007) and intensity (Parks *et al.* 2010), while some humpback whales respond to low-frequency active sonar playbacks by increasing song length (Miller *el al.* 2000). These behavioral responses could also have adverse effects on marine mammals.

Mysticetes: Baleen whales generally tend to avoid operating airguns, but avoidance radii are quite variable. Whales are often reported to show no overt reactions to airgun pulses at distances beyond a few kilometers, even though the airgun pulses remain well above ambient noise levels out to much longer distances (reviewed in Richardson *et al.* 1995; Gordon *et al.* 2004). However, studies done since the late 1990s of migrating humpback and migrating bowhead whales show reactions, including avoidance, that sometimes extend to greater distances than documented earlier. Therefore, it appears that behavioral disturbance can vary greatly depending on context, and not just received levels alone. Avoidance distances often exceed the distances at which boat-based observers can see whales, so observations from the source vessel can be biased. Observations over broader areas may be needed to determine the range of potential effects of some large-source seismic surveys where effects on cetaceans may extend to considerable distances (Richardson *et al.* 1999; Moore and Angliss 2006). Longer-range observations, when required, can sometimes be obtained via systematic aerial surveys or aircraft-based observations of behavior (e.g., Richardson *et al.* 1986, 1999; Miller *et al.* 1999, 2005; Yazvenko *et al.* 2007a, 2007b) or by use of observers on one or more support vessels operating in coordination with the seismic vessel (e.g., Smultea *et al.* 2004; Johnson *et al.* 2007). However, the presence of other vessels near the source vessel can, at least at times, reduce sightability of cetaceans from the source vessel (Beland *et al.* 2009), thus complicating interpretation of sighting data.

Some baleen whales show considerable tolerance of seismic pulses. However, when the pulses are strong enough, avoidance or other behavioral changes become evident. Because the responses become less obvious with diminishing received sound level, it has been difficult to determine the maximum distance (or minimum received sound level) at which reactions to seismic activity become evident and, hence, how many whales are affected.

Studies of gray, bowhead, and humpback whales have determined that received levels of pulses in the 160–170 dB re 1 μPa (rms) range seem to cause obvious avoidance behavior in a substantial fraction of the animals exposed (McCauley *et al.* 1998, 1999, 2000). In many areas, seismic pulses diminish to these levels at distances ranging from 4–15 km from the source. A substantial proportion of the baleen whales within such distances may show avoidance or other strong disturbance reactions to the operating airgun array. Some extreme examples including migrating bowhead whales avoiding considerably larger distances (20–30 km) and lower received sound levels (120–130 dB re 1 μPa (rms)) when exposed to airguns from seismic surveys. Also, even in cases where there is no conspicuous avoidance or change in activity upon exposure to sound pulses from distant seismic operations, there are sometimes subtle changes in behavior (e.g., surfacing–respiration–dive cycles) that are only evident through detailed statistical analysis (e.g., Richardson *et al.* 1986; Gailey *et al.* 2007).

Data on short-term reactions by cetaceans to impulsive noises are not necessarily indicative of long-term or biologically significant effects. It is not known whether impulsive sounds affect reproductive rate or distribution and habitat use in subsequent days or years. However, gray whales have continued to migrate annually along the west coast of North America despite intermittent seismic exploration (and much ship traffic) in that area for decades (Appendix A in Malme *et al.* 1984; Richardson *et al.* 1995), and there has been a substantial increase in the population over recent decades (Allen and Angliss 2010). The western Pacific gray whale population did not seem affected by a seismic survey in its feeding ground during a prior year (Johnson *et al.* 2007). Similarly, bowhead whales have continued to travel to the eastern Beaufort Sea each summer despite seismic exploration in their summer and autumn range for many years (Richardson *et al.* 1987), and their numbers have increased notably (Allen and Angliss 2010). Bowheads also have been observed over periods of days or weeks in areas ensonified repeatedly by seismic pulses (Richardson *et al.* 1987; Harris *et al.* 2007). However, it is generally not known whether the same individual bowheads were involved in these repeated observations (within and between years) in strongly ensonified areas.

Odontocete: Relatively little systematic information is available about reactions of toothed whales to airgun pulses. A few studies similar to the more extensive baleen whale/seismic pulse work summarized above have been reported for toothed whales. However, there are recent systematic data on sperm whales (e.g., Gordon *et al.* 2006; Madsen *et al.* 2006; Winsor and Mate 2006; Jochens *et al.* 2008; Miller *et al.* 2009) and beluga whales (e.g., Miller *et al.* 2005). There is also an increasing amount of information about responses of various odontocetes to seismic surveys based on monitoring studies (e.g., Stone 2003; Smultea *et al.* 2004; Moulton and Miller 2005; Holst *et al.* 2006; Stone and Tasker 2006; Potter *et al.* 2007; Hauser *et al.* 2008; Holst and Smultea 2008; Weir 2008; Barkaszi *et al.* 2009; Richardson *et al.* 2009).

Dolphins and porpoises are often seen by observers on active seismic vessels, occasionally at close distances (e.g., bow riding). Marine mammal monitoring data during seismic surveys often show that animal detection rates drop during the firing of seismic airguns, indicating that animals may be avoiding the vicinity of the seismic area (Smultea *et al.* 2004; Holst *et al.* 2006; Hauser *et al.* 2008; Holst and Smultea 2008; Richardson *et al.* 2009). Also, belugas summering in the Canadian Beaufort Sea showed larger-scale avoidance, tending to avoid waters out to 10–20 km from operating seismic vessels (Miller *et al.* 2005). In contrast, recent studies show little evidence of conspicuous reactions by sperm whales to airgun pulses, contrary to earlier indications (e.g., Gordon *et al.* 2006; Stone and Tasker 2006; Winsor and Mate 2006; Jochens *et al.* 2008), except the lower buzz (echolocation signals) rates that were detected during exposure of airgun pulses (Miller *et al.* 2009).

There are almost no specific data on responses of beaked whales to seismic surveys, but it is likely that most if not all species show strong avoidance. There is increasing evidence that some beaked whales may strand after exposure to strong noise from tactical military mid-frequency sonars. Whether they ever do so in response to seismic survey noise is unknown. Northern bottlenose whales seem to continue to call when exposed to pulses from distant seismic vessels.

For delphinids, and possibly the Dall's porpoise, the available data suggest that a ≥170 dB re 1 μPa (rms) disturbance criterion (rather than ≥160 dB) would be appropriate. With a medium-to-large airgun array, received levels typically diminish to 170 dB within 1–4 km, whereas levels typically remain above 160 dB out to 4–15 km (e.g., Tolstoy *et al.* 2009). Reaction distances for delphinids are more consistent with the typical 170 dB re 1 μPa (rms) distances. Stone (2003) and Stone and Tasker (2006) reported that all small odontocetes (including killer whales) observed during seismic surveys in UK waters remained significantly further from the source during periods of shooting on surveys with large volume airgun arrays than during periods without airgun shooting.

Due to their relatively higher frequency hearing ranges when compared to mysticetes, odontocetes may have stronger responses to mid- and high-frequency sources such as sub-bottom profilers, side scan sonar, and echo sounders than mysticetes (Richardson *et al.* 1995; Southall *et al.* 2007).

Pinnipeds: Few studies of the reactions of pinnipeds to noise from open-water seismic exploration have been published (for review of the early literature, see Richardson *et al.* 1995). However, pinnipeds have been observed during a number of seismic monitoring studies. Monitoring in the Beaufort Sea during 1996–2002 provided a substantial amount of information on avoidance responses (or lack thereof) and associated behavior. Additional monitoring of that type has been done in the Beaufort and Chukchi Seas in 2006–2009. Pinnipeds exposed to seismic surveys have also been observed during seismic surveys along the U.S. west coast. Also, there are data on the reactions of pinnipeds to various other related types of impulsive sounds.

Early observations provided considerable evidence that pinnipeds are often quite tolerant of strong pulsed sounds. During seismic exploration off Nova Scotia, gray seals exposed to noise from airguns and linear explosive charges reportedly did not react strongly (J. Parsons in Greene *et al.* 1985). An airgun caused an initial startle reaction among South African fur seals but was ineffective in scaring them away from fishing gear. Pinnipeds in both water and air sometimes tolerate strong noise pulses from non-explosive and explosive scaring devices, especially if attracted to the area for feeding or reproduction (Mate and Harvey 1987; Reeves *et al.* 1996). Thus, pinnipeds are expected to be rather tolerant of, or to habituate to, repeated underwater sounds from distant seismic sources, at least when the animals are strongly attracted to the area.

In summary, visual monitoring from seismic vessels has shown only slight (if any) avoidance of airguns by pinnipeds, and only slight (if any) changes in

behavior. These studies show that many pinnipeds do not avoid the area within a few hundred meters of an operating airgun array. However, based on the studies with large sample size, or observations from a separate monitoring vessel, or radio telemetry, it is apparent that some phocid seals do show localized avoidance of operating airguns. The limited nature of this tendency for avoidance is a concern. It suggests that one cannot rely on pinnipeds to move away, or to move very far away, before received levels of sound from an approaching seismic survey vessel approach those that may cause hearing impairment.

(2) Masking

Masking occurs when noise and signals (that animal utilizes) overlap at both spectral and temporal scales. Chronic exposure to elevated sound levels could cause masking at particular frequencies for marine mammals, which utilize sound for important biological functions. Masking can interfere with detection of acoustic signals used for orientation, communication, finding prey, and avoiding predators. Marine mammals that experience severe (high intensity and extended duration) acoustic masking could potentially suffer reduced fitness, which could lead to adverse effects on survival and reproduction.

For the airgun noise generated from the proposed marine seismic survey, these are low frequency (under 1 kHz) pulses with extremely short durations (in the scale of milliseconds). Lower frequency man-made noises are more likely to affect detection of communication calls and other potentially important natural sounds such as surf and prey noise. There is little concern regarding masking due to the brief duration of these pulses and relatively longer silence between airgun shots (9–12 seconds) near the noise source, however, at long distances (over tens of kilometers away) in deep water, due to multipath propagation and reverberation, the durations of airgun pulses can be ''stretched'' to seconds with long decays (Madsen *et al.* 2006; Clark and Gagnon 2006). Therefore it could affect communication signals used by low frequency mysticetes when they occur near the noise band and thus reduce the communication space of animals (e.g., Clark *et al.* 2009a, 2009b) and affect their vocal behavior (e.g., Foote *et al.* 2004; Holt *et al.* 2009). Further, in areas of shallow water, multipath propagation of airgun pulses could be more profound, thus affecting communication signals from marine mammals even at close distances. Average ambient noise in areas where received seismic noises are heard can be elevated. At long distances, however, the intensity of the noise is greatly reduced. Nevertheless, partial informational and energetic masking of different degrees could affect signal receiving in some marine mammals within the ensonified areas. Additional research is needed to further address these effects.

Although masking effects of pulsed sounds on marine mammal calls and other natural sounds are expected to be limited, there are few specific studies on this. Some whales continue calling in the presence of seismic pulses and whale calls often can be heard between the seismic pulses (e.g., Richardson *et al.* 1986; McDonald *et al.* 1995; Greene *et al.* 1999a, 1999b; Nieukirk *et al.* 2004; Smultea *et al.* 2004; Holst *et al.* 2005a, 2005b, 2006; Dunn and Hernandez 2009).

Among the odontocetes, there has been one report that sperm whales ceased calling when exposed to pulses from a very distant seismic ship (Bowles *et al.* 1994). However, more recent studies of sperm whales found that they continued calling in the presence of seismic pulses (Madsen *et al.* 2002; Tyack *et al.* 2003; Smultea *et al.* 2004; Holst *et al.* 2006; Jochens *et al.* 2008). Madsen *et al.* (2006) noted that airgun sounds would not be expected to mask sperm whale calls given the intermittent nature of airgun pulses. Dolphins and porpoises are also commonly heard calling while airguns are operating (Gordon *et al.* 2004; Smultea *et al.* 2004; Holst *et al.* 2005a, 2005b; Potter *et al.* 2007). Masking effects of seismic pulses are expected to be negligible in the case of the smaller odontocetes, given the intermittent nature of seismic pulses plus the fact that sounds important to them are predominantly at much higher frequencies than are the dominant components of airgun sounds.

Pinnipeds have best hearing sensitivity and/or produce most of their sounds at frequencies higher than the dominant components of airgun sound, but there is some overlap in the frequencies of the airgun pulses and the calls. However, the intermittent nature of airgun pulses presumably reduces the potential for masking.

Marine mammals are thought to be able to compensate for masking by adjusting their acoustic behavior such as shifting call frequencies, and increasing call volume and vocalization rates, as discussed earlier (e.g., Miller et al. 2000; Parks *et al.* 2007; Di Iorio and Clark 2009; Parks *et al.* 2010); the biological significance of these modifications is still unknown.

(3) Hearing Impairment

Marine mammals exposed to high intensity sound repeatedly or for prolonged periods can experience hearing threshold shift (TS), which is the loss of hearing sensitivity at certain frequency ranges (Kastak *et al.* 1999; Schlundt *et al.* 2000; Finneran *et al.* 2002; 2005). TS can be permanent (PTS), in which case the loss of hearing sensitivity is unrecoverable, or temporary (TTS), in which case the animal's hearing threshold will recover over time (Southall *et al.* 2007). Marine mammals that experience TTS or PTS will have reduced sensitivity at the frequency band of the TS, which may affect their capability of communication, orientation, or prey detection. The degree of TS depends on the intensity of the received levels the animal is exposed to, and the frequency at which TS occurs depends on the frequency of the received noise. It has been shown that in most cases, TS occurs at the frequencies approximately one-octave above that of the received noise. Repeated noise exposure that leads to TTS could cause PTS. For transient sounds, the sound level necessary to cause TTS is inversely related to the duration of the sound.

TTS

TTS is the mildest form of hearing impairment that can occur during exposure to a strong sound (Kryter 1985). While experiencing TTS, the hearing threshold rises and a sound must be stronger in order to be heard. It is a temporary phenomenon, and (especially when mild) is not considered to represent physical damage or ''injury'' (Southall *et al.* 2007). Rather, the onset of TTS is an indicator that, if the animal is exposed to higher levels of that sound, physical damage is ultimately a possibility.

The magnitude of TTS depends on the level and duration of noise exposure, and to some degree on frequency, among other considerations (Kryter 1985; Richardson *et al.* 1995; Southall *et al.* 2007). For sound exposures at or somewhat above the TTS threshold, hearing sensitivity recovers rapidly after exposure to the noise ends. In terrestrial mammals, TTS can last from minutes or hours to (in cases of strong TTS) days. Only a few data have been obtained on sound levels and durations necessary to elicit mild TTS in marine mammals (none in mysticetes), and none of the published data concern TTS elicited by exposure to multiple pulses of sound during operational seismic surveys (Southall *et al.* 2007).

For toothed whales, experiments on a bottlenose dolphin (*Tursiops truncates*) and beluga whale showed that exposure to a single watergun impulse at a received level of 207 kPa (or 30 psi) peak-to-peak (p-p), which is equivalent to 228 dB re 1 μPa (p-p), resulted in a 7 and 6 dB TTS in the beluga whale at 0.4 and 30 kHz, respectively. Thresholds returned to within 2 dB of the pre-exposure level within 4 minutes of the exposure (Finneran *et al.* 2002). No TTS was observed in the bottlenose dolphin.

Finneran *et al.* (2005) further examined the effects of tone duration on TTS in bottlenose dolphins. Bottlenose dolphins were exposed to 3 kHz tones (non-impulsive) for periods of 1, 2, 4 or 8 seconds (s), with hearing tested at 4.5 kHz. For 1-s exposures, TTS occurred with SELs of 197 dB, and for exposures >1 s, SEL >195 dB resulted in TTS (SEL is equivalent to energy flux, in dB re 1 μPa^2-s). At an SEL of 195 dB, the mean TTS (4 min after exposure) was 2.8 dB. Finneran *et al.* (2005) suggested that an SEL of 195 dB is the likely threshold for the onset of TTS in dolphins and belugas exposed to tones of durations 1—8 s (i.e., TTS onset occurs at a near-constant SEL, independent of exposure duration). That implies that, at least for non-impulsive tones, a doubling of exposure time results in a 3 dB lower TTS threshold.

However, the assumption that, in marine mammals, the occurrence and magnitude of TTS is a function of cumulative acoustic energy (SEL) is probably an oversimplification. Kastak *et al.* (2005) reported preliminary evidence from pinnipeds that, for prolonged non-impulse noise, higher SELs were required to elicit a given TTS if exposure duration was short than if it was longer, i.e., the results were not fully consistent with an equal-energy model to predict TTS onset. Mooney *et al.* (2009a) showed this in a bottlenose dolphin exposed to octave-band non-impulse noise ranging from 4 to 8 kHz at SPLs of 130 to 178 dB re 1 μPa for periods of 1.88 to 30 minutes (min). Higher SELs were required to induce a given TTS if exposure duration was short than if it was longer. Exposure of the aforementioned bottlenose dolphin to a sequence of brief sonar signals showed that, with those brief (but non-impulse) sounds, the received energy (SEL) necessary to elicit TTS was higher than was the case with exposure to the more prolonged octave-band noise (Mooney *et al.* 2009b). Those authors concluded that, when using (non-impulse) acoustic signals of duration ~0.5 s, SEL must be at least 210–214 dB re 1 μPa^2-s to induce TTS in the bottlenose dolphin. The most recent studies conducted by Finneran *et al.* also support the notion that exposure duration has a more significant influence compared to SPL as the duration increases, and that TTS growth data are better represented as functions of SPL and duration rather than SEL alone (Finneran *et al.* 2010a, 2010b). In addition, Finneran *et al.* (2010b) conclude that when animals are exposed to intermittent noises, there is recovery of hearing during the quiet intervals between exposures through the accumulation of TTS across multiple exposures. Such findings suggest that when exposed to multiple seismic pulses, partial hearing recovery also occurs during the seismic pulse intervals.

For baleen whales, there are no data, direct or indirect, on levels or properties of sound that are required to induce TTS. The frequencies to which baleen whales are most sensitive are lower than those to which odontocetes are most sensitive, and natural ambient noise levels at those low frequencies tend to be higher (Urick 1983). As a result, auditory thresholds of baleen whales within their frequency band of best hearing are believed to be higher (less sensitive) than are those of odontocetes at their best frequencies (Clark and Ellison 2004). From this, it is suspected that received levels causing TTS onset may also be higher in baleen whales. However, no cases of TTS are expected given the small size of the airguns proposed to be used and the strong likelihood that baleen whales (especially migrating bowheads) would avoid the approaching airguns (or vessel) before being exposed to levels high enough for there to be any possibility of TTS.

In pinnipeds, TTS thresholds associated with exposure to brief pulses (single or multiple) of underwater sound have not been measured. Initial evidence from prolonged exposures suggested that some pinnipeds may incur TTS at somewhat lower received levels than do small odontocetes exposed for similar durations (Kastak *et al.* 1999; 2005). However, more recent indications are that TTS onset in the most sensitive pinniped species studied (harbor seal, which is closely related to the ringed seal) may occur at a similar SEL as in odontocetes (Kastak *et al.* 2004).

Most cetaceans show some degree of avoidance of seismic vessels operating an airgun array (see above). It is unlikely that these cetaceans would be exposed to airgun pulses at a sufficiently high level for a sufficiently long period to cause more than mild TTS, given the relative movement of the vessel and the marine mammal. TTS would be more likely in any odontocetes that bow- or wake-ride or otherwise linger near the airguns. However, while bow- or wake-riding, odontocetes would be at the surface and thus not exposed to strong sound pulses given the pressure release and Lloyd Mirror effects at the surface. But if bow- or wake-riding animals were to dive intermittently near airguns, they would be exposed to strong sound pulses, possibly repeatedly.

If some cetaceans did incur mild or moderate TTS through exposure to airgun sounds in this manner, this would very likely be a temporary and reversible phenomenon. However, even a temporary reduction in hearing sensitivity could be deleterious in the event that, during that period of reduced sensitivity, a marine mammal needed its full hearing sensitivity to detect approaching predators, or for some other reason.

Some pinnipeds show avoidance reactions to airguns, but their avoidance reactions are generally not as strong or consistent as those of cetaceans. Pinnipeds occasionally seem to be attracted to operating seismic vessels. There are no specific data on TTS thresholds of pinnipeds exposed to single or multiple low-frequency pulses. However, given the indirect indications of a lower TTS threshold for the harbor seal than for odontocetes exposed to impulse sound (see above), it is possible that some pinnipeds close to a large airgun array could incur TTS.

NMFS currently typically includes mitigation requirements to ensure that cetaceans and pinnipeds are not exposed to pulsed underwater noise at received levels exceeding, respectively, 180 and 190 dB re 1 μPa (rms). The 180/190 dB acoustic criteria were taken from recommendations by an expert panel of the High Energy Seismic Survey (HESS) Team that performed an assessment on noise impacts by seismic airguns to marine mammals in 1997, although the HESS Team recommended a 180-dB limit for pinnipeds in California (HESS 1999). The 180 and 190 dB re 1 μPa (rms) levels have not been considered to be the levels above which TTS might occur. Rather, they were the received levels above which, in the view of a panel of bioacoustics specialists convened by NMFS before TTS measurements for marine mammals started to become available, one could not be certain that there would be no injurious effects, auditory or otherwise, to marine mammals. As summarized above, data that are now available imply that TTS is unlikely to occur in various odontocetes (and probably mysticetes as

well) unless they are exposed to a sequence of several airgun pulses stronger than 190 dB re 1 μPa (rms). On the other hand, for the harbor seal, harbor porpoise, and perhaps some other species, TTS may occur upon exposure to one or more airgun pulses whose received level equals the NMFS ''do not exceed'' value of 190 dB re 1 μPa (rms). That criterion corresponds to a single-pulse SEL of 175–180 dB re 1 μPa^2-s in typical conditions, whereas TTS is suspected to be possible in harbor seals and harbor porpoises with a cumulative SEL of ~171 and ~164 dB re 1 μPa^2-s, respectively.

It has been shown that most large whales and many smaller odontocetes (especially the harbor porpoise) show at least localized avoidance of ships and/or seismic operations. Even when avoidance is limited to the area within a few hundred meters of an airgun array, that should usually be sufficient to avoid TTS based on what is currently known about thresholds for TTS onset in cetaceans. In addition, ramping up airgun arrays, which is standard operational protocol for many seismic operators, may allow cetaceans near the airguns at the time of startup (if the sounds are aversive) to move away from the seismic source and to avoid being exposed to the full acoustic output of the airgun array. Thus, most baleen whales likely will not be exposed to high levels of airgun sounds provided the ramp-up procedure is applied. Likewise, many odontocetes close to the trackline are likely to move away before the sounds from an approaching seismic vessel become sufficiently strong for there to be any potential for TTS or other hearing impairment. Hence, there is little potential for baleen whales or odontocetes that show avoidance of ships or airguns to be close enough to an airgun array to experience TTS. Nevertheless, even if marine mammals were to experience TTS, the magnitude of the TTS is expected to be mild and brief, only in a few decibels for minutes.

PTS

When PTS occurs, there is physical damage to the sound receptors in the ear. In some cases, there can be total or partial deafness, whereas in other cases, the animal has an impaired ability to hear sounds in specific frequency ranges (Kryter 1985). Physical damage to a mammal's hearing apparatus can occur if it is exposed to sound impulses that have very high peak pressures, especially if they have very short rise times. (Rise time is the interval required for sound pressure to increase from the baseline pressure to peak pressure.)

There is no specific evidence that exposure to pulses of airgun sound can cause PTS in any marine mammal, even with large arrays of airguns. However, given the likelihood that some mammals close to an airgun array might incur at least mild TTS (see above), there has been further speculation about the possibility that some individuals occurring very close to airguns might incur PTS (e.g., Richardson *et al.* 1995; Gedamke *et al.* 2008). Single or occasional occurrences of mild TTS are not indicative of permanent auditory damage, but repeated or (in some cases) single exposures to a level well above that causing TTS onset might elicit PTS.

Relationships between TTS and PTS thresholds have not been studied in marine mammals, but are assumed to be similar to those in humans and other terrestrial mammals (Southall *et al.* 2007). Based on data from terrestrial mammals, a precautionary assumption is that the PTS threshold for impulse sounds (such as airgun pulses as received close to the source) is at least 6 dB higher than the TTS threshold on a peak-pressure basis, and probably >6 dB higher (Southall *et al.* 2007). The low-to-moderate levels of TTS that have been induced in captive odontocetes and pinnipeds during controlled studies of TTS have been confirmed to be temporary, with no measurable residual PTS (Kastak *et al.* 1999; Schlundt *et al.* 2000; Finneran *et al.* 2002; 2005; Nachtigall *et al.* 2003; 2004). However, very prolonged exposure to sound strong enough to elicit TTS, or shorter-term exposure to sound levels well above the TTS threshold, can cause PTS, at least in terrestrial mammals (Kryter 1985). In terrestrial mammals, the received sound level from a single non-impulsive sound exposure must be far above the TTS threshold for any risk of permanent hearing damage (Kryter 1994; Richardson *et al.* 1995; Southall *et al.* 2007). However, there is special concern about strong sounds whose pulses have very rapid rise times. In terrestrial mammals, there are situations when pulses with rapid rise times (e.g., from explosions) can result in PTS even though their peak levels are only a few dB higher than the level causing slight TTS. The rise time of airgun pulses is fast, but not as fast as that of an explosion.

Some factors that contribute to onset of PTS, at least in terrestrial mammals, are as follows:

- exposure to a single very intense sound,
- fast rise time from baseline to peak pressure,
- repetitive exposure to intense sounds that individually cause TTS but not PTS, and
- recurrent ear infections or (in captive animals) exposure to certain drugs.

Cavanagh (2000) reviewed the thresholds used to define TTS and PTS. Based on this review and SACLANT (1998), it is reasonable to assume that PTS might occur at a received sound level 20 dB or more above that inducing mild TTS. However, for PTS to occur at a received level only 20 dB above the TTS threshold, the animal probably would have to be exposed to a strong sound for an extended period, or to a strong sound with a rather rapid rise time.

More recently, Southall *et al.* (2007) estimated that received levels would need to exceed the TTS threshold by at least 15 dB, on an SEL basis, for there to be risk of PTS. Thus, for cetaceans exposed to a sequence of sound pulses, they estimate that the PTS threshold might be an M-weighted SEL (for the sequence of received pulses) of ~198 dB re 1 μPa^2-s. Additional assumptions had to be made to derive a corresponding estimate for pinnipeds, as the only available data on TTS-thresholds in pinnipeds pertained to nonimpulse sound (see above). Southall *et al.* (2007) estimated that the PTS threshold could be a cumulative SEL of ~186 dB re 1 μPa^2-s in the case of a harbor seal exposed to impulse sound. The PTS threshold for the California sea lion and northern elephant seal would probably be higher given the higher TTS thresholds in those species. Southall *et al.* (2007) also note that, regardless of the SEL, there is concern about the possibility of PTS if a cetacean or pinniped received one or more pulses with peak pressure exceeding 230 or 218 dB re 1 μPa, respectively. Thus, PTS might be expected upon exposure of cetaceans to either SEL ≥198 dB re 1 μPa^2-s or peak pressure ≥230 dB re 1 μPa. Corresponding proposed dual criteria for pinnipeds (at least harbor seals) are ≥186 dB SEL and ≥ 218 dB peak pressure (Southall *et al.* 2007). These estimates are all first approximations, given the limited underlying data, assumptions, species differences, and evidence that the ''equal energy'' model may not be entirely correct.

Sound impulse duration, peak amplitude, rise time, number of pulses, and inter-pulse interval are the main factors thought to determine the onset and extent of PTS. Ketten (1994) has noted that the criteria for differentiating the sound pressure levels that result in PTS (or TTS) are location and species

specific. PTS effects may also be influenced strongly by the health of the receiver's ear.

As described above for TTS, in estimating the amount of sound energy required to elicit the onset of TTS (and PTS), it is assumed that the auditory effect of a given cumulative SEL from a series of pulses is the same as if that amount of sound energy were received as a single strong sound. There are no data from marine mammals concerning the occurrence or magnitude of a potential partial recovery effect between pulses. In deriving the estimates of PTS (and TTS) thresholds quoted here, Southall *et al.* (2007) made the precautionary assumption that no recovery would occur between pulses.

It is unlikely that an odontocete would remain close enough to a large airgun array for sufficiently long to incur PTS. There is some concern about bowriding odontocetes, but for animals at or near the surface, auditory effects are reduced by Lloyd's mirror and surface release effects. The presence of the vessel between the airgun array and bow-riding odontocetes could also, in some but probably not all cases, reduce the levels received by bow-riding animals (e.g., Gabriele and Kipple 2009). The TTS (and thus PTS) thresholds of baleen whales are unknown but, as an interim measure, assumed to be no lower than those of odontocetes. Also, baleen whales generally avoid the immediate area around operating seismic vessels, so it is unlikely that a baleen whale could incur PTS from exposure to airgun pulses. The TTS (and thus PTS) thresholds of some pinnipeds (e.g., harbor seal) as well as the harbor porpoise may be lower (Kastak *et al.* 2005; Southall *et al.* 2007; Lucke *et al.* 2009). If so, TTS and potentially PTS may extend to a somewhat greater distance for those animals. Again, Lloyd's mirror and surface release effects will ameliorate the effects for animals at or near the surface.

(4) Non-Auditory Physical Effects

Non-auditory physical effects might occur in marine mammals exposed to strong underwater pulsed sound. Possible types of non-auditory physiological effects or injuries that theoretically might occur in mammals close to a strong sound source include neurological effects, bubble formation, and other types of organ or tissue damage. Some marine mammal species (i.e., beaked whales) may be especially susceptible to injury and/or stranding when exposed to intense sounds. However, there is no definitive evidence that any of these effects occur even for marine mammals in close proximity to large arrays of airguns, and beaked whales do not occur in the proposed project area. In addition, marine mammals that show behavioral avoidance of seismic vessels, including most baleen whales, some odontocetes (including belugas), and some pinnipeds, are especially unlikely to incur non-auditory impairment or other physical effects.

Therefore, it is unlikely that such effects would occur during TGS' proposed seismic surveys given the brief duration of exposure, the small sound sources, and the planned monitoring and mitigation measures described later in this document.

Additional non-auditory effects include elevated levels of stress response (Wright *et al.* 2007; Wright and Highfill 2007). Although not many studies have been done on noise-induced stress in marine mammals, extrapolation of information regarding stress responses in other species seems applicable because the responses are highly consistent among all species in which they have been examined to date (Wright *et al.* 2007). Therefore, it is reasonable to conclude that noise acts as a stressor to marine mammals. Furthermore, given that marine mammals will likely respond in a manner consistent with other species studied, repeated and prolonged exposures to stressors (including or induced by noise) could potentially be problematic for marine mammals of all ages. Wright *et al.* (2007) state that a range of issues may arise from an extended stress response including, but not limited to, suppression of reproduction (physiologically and behaviorally), accelerated aging and sickness-like symptoms. However, as mentioned above, TGS' proposed activity is not expected to result in these severe effects due to the nature of the potential sound exposure.

(5) Stranding and Mortality

Marine mammals close to underwater detonations can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.* 1993; Ketten 1995). Airgun pulses are less energetic and their peak amplitudes have slower rise times, while stranding and mortality events would include other energy sources (acoustical or shock wave) far beyond just seismic airguns. To date, there is no evidence that serious injury, death, or stranding by marine mammals can occur from exposure to airgun pulses, even in the case of large airgun arrays.

However, in numerous past IHA notices for seismic surveys, commenters have referenced two stranding events allegedly associated with seismic activities, one off Baja California and a second off Brazil. NMFS has addressed this concern several times, and, without new information, does not believe that this issue warrants further discussion. For information relevant to strandings of marine mammals, readers are encouraged to review NMFS' response to comments on this matter found in 69 FR 74906 (December 14, 2004), 71 FR 43112 (July 31, 2006), 71 FR 50027 (August 24, 2006), and 71 FR 49418 (August 23, 2006).

It should be noted that strandings related to sound exposure have not been recorded for marine mammal species in the Chukchi or Beaufort seas. NMFS notes that in the Beaufort and Chukchi seas, aerial surveys have been conducted by BOEM (previously MMS) and industry during periods of industrial activity (and by BOEM during times with no activity). No strandings or marine mammals in distress have been observed during these surveys and none have been reported by North Slope Borough inhabitants. In addition, there are very few instances that seismic surveys in general have been linked to marine mammal strandings, other than those mentioned above. As a result, NMFS does not expect any marine mammals will incur serious injury or mortality in the Arctic Ocean or strand as a result of the proposed marine survey.

Potential Effects of Sonar Signals

Industrial standard navigational sonars would be used during TGS' proposed 2D seismic surveys program for navigation safety. Source characteristics of the representative generic equipment are discussed in the ''Description of Specific Activity'' section above. In general, the potential effects of this equipment on marine mammals are similar to those from the airgun, except the magnitude of the impacts is expected to be much less due to the lower intensity, higher frequencies, and with downward narrow beam patterns. In some cases, due to the fact that the operating frequencies of some of this equipment (e.g., Kongsberg EA600 with frequencies up to 200 kHz) are above the hearing ranges of marine mammals, they are not expected to have any impacts to marine mammals.

Vessel Sounds

In addition to the noise generated from seismic airguns and active sonar systems, two vessels would be involved in the operations, including a source vessel and a support vessel that provides marine mammal monitoring

and logistic support. Sounds from boats and vessels have been reported extensively (Greene and Moore 1995; Blackwell and Greene 2002; 2005; 2006). Numerous measurements of underwater vessel sound have been performed in support of recent industry activity in the Chukchi and Beaufort Seas. Results of these measurements were reported in various 90-day and comprehensive reports since 2007 (e.g., Aerts *et al.* 2008; Hauser *et al.* 2008; Brueggeman 2009; Ireland *et al.* 2009; O'Neill and McCrodan 2011; Chorney *et al.* 2011; McPherson and Warner 2012). For example, Garner and Hannay (2009) estimated sound pressure levels of 100 dB at distances ranging from approximately 1.5 to 2.3 mi (2.4 to 3.7 km) from various types of barges. MacDonald *et al.* (2008) estimated higher underwater SPLs from the seismic vessel *Gilavar* of 120 dB at approximately 13 mi (21 km) from the source, although the sound level was only 150 dB at 85 ft (26 m) from the vessel. Compared to airgun pulses, underwater sound from vessels is generally at relatively low frequencies.

The primary sources of sounds from all vessel classes are propeller cavitation, propeller singing, and propulsion or other machinery. Propeller cavitation is usually the dominant noise source for vessels (Ross 1976). Propeller cavitation and singing are produced outside the hull, whereas propulsion or other machinery noise originates inside the hull. There are additional sounds produced by vessel activity, such as pumps, generators, flow noise from water passing over the hull, and bubbles breaking in the wake. Source levels from various vessels would be empirically measured before the start of the seismic surveys.

Anticipated Effects on Habitat

The primary potential impacts to marine mammals and other marine species are associated with elevated sound levels produced by airguns and vessels operating in the area. However, other potential impacts to the surrounding habitat from physical disturbance are also possible.

With regard to fish as a prey source for cetaceans and pinnipeds, fish are known to hear and react to sounds and to use sound to communicate (Tavolga *et al.* 1981) and possibly avoid predators (Wilson and Dill 2002). Experiments have shown that fish can sense both the strength and direction of sound (Hawkins 1981). Primary factors determining whether a fish can sense a sound signal, and potentially react to it, are the frequency of the signal and the strength of the signal in relation to the natural background noise level.

The level of sound at which a fish will react or alter its behavior is usually well above the detection level. Fish have been found to react to sounds when the sound level increased to about 20 dB above the detection level of 120 dB (Ona 1988); however, the response threshold can depend on the time of year and the fish's physiological condition (Engas *et al.* 1993). In general, fish react more strongly to pulses of sound rather than non-pulse signals (such as noise from vessels) (Blaxter *et al.* 1981), and a quicker alarm response is elicited when the sound signal intensity rises rapidly compared to sound rising more slowly to the same level.

Investigations of fish behavior in relation to vessel noise (Olsen *et al.* 1983; Ona 1988; Ona and Godo 1990) have shown that fish react when the sound from the engines and propeller exceeds a certain level. Avoidance reactions have been observed in fish such as cod and herring when vessels approached close enough that received sound levels are 110 dB to 130 dB (Nakken 1992; Olsen 1979; Ona and Godo 1990; Ona and Toresen 1988). However, other researchers have found that fish such as polar cod, herring, and capeline are often attracted to vessels (apparently by the noise) and swim toward the vessel (Rostad *et al.* 2006). Typical sound source levels of vessel noise in the audible range for fish are 150 dB to 170 dB (Richardson *et al.* 1995).

Further, during the seismic survey only a small fraction of the available habitat would be ensonified at any given time. Disturbance to fish species would be short-term and fish would return to their pre-disturbance behavior once the seismic activity ceases (McCauley *et al.* 2000a, 2000b; Santulli *et al.* 1999; Pearson *et al.* 1992). Thus, the proposed survey would have little, if any, impact on the abilities of marine mammals to feed in the area where seismic work is planned.

Some mysticetes, including bowhead whales, feed on concentrations of zooplankton. Some feeding bowhead whales may occur in the Alaskan Beaufort Sea in July and August, and others feed intermittently during their westward migration in September and October (Richardson and Thomson [eds.] 2002; Lowry *et al.* 2004). A reaction by zooplankton to a seismic impulse would only be relevant to whales if it caused concentrations of zooplankton to scatter. Pressure changes of sufficient magnitude to cause that type of reaction would probably occur only very close to the source. Impacts on zooplankton behavior are predicted to be negligible, and that would translate into negligible impacts on feeding mysticetes. Thus, the proposed activity is not expected to have any habitat-related effects on prey species that could cause significant or long-term consequences for individual marine mammals or their populations.

Potential Impacts on Availability of Affected Species or Stock for Taking for Subsistence Uses

Subsistence hunting is an essential aspect of Inupiat Native life, especially in rural coastal villages. The Inupiat participate in subsistence hunting activities in and around the Chukchi Sea. The animals taken for subsistence provide a significant portion of the food that will last the community through the year. Marine mammals represent on the order of 60–80% of the total subsistence harvest. Along with the nourishment necessary for survival, the subsistence activities strengthen bonds within the culture, provide a means for educating the young, provide supplies for artistic expression, and allow for important celebratory events.

Potential Impacts to Subsistence Uses

NMFS has defined ''unmitigable adverse impact'' in 50 CFR 216.103 as: ''. . . an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.''

(1) Bowhead Whales

TGS' planned seismic surveys would have no or negligible effects on bowhead whale harvest activities. Noise and general activity associated with marine surveys and operation of vessels has the potential to harass bowhead whales. However, though temporary diversions of the swim path of migrating whales have been documented, the whales have generally been observed to resume their initial migratory route. The proposed open-water seismic surveys and vessel noise could affect subsistence hunts by placing the animals further offshore or otherwise at a greater distance from villages thereby increasing the difficulty of the hunt or

retrieval of the harvest, or creating a safety risk to the whalers.

Ten primary coastal Alaskan villages deploy whaling crews during whale migrations. Around the TGS' proposed project area in the Chukchi Sea, the primary bowhead hunting villages that could be affected are Barrow, Wainwright, and Point Hope. Whaling crews in Barrow hunt in both the spring and the fall (Funk and Galginaitis 2005). The primary bowhead whale hunt in Barrow occurs during spring, while the fall hunt is used to meet the quota and seek strikes that can be transferred from other communities. In the spring, the whales are hunted along leads that occur when the pack ice starts deteriorating. This tends to occur between the first week of April through May in Barrow and the first week of June in Wainwright, well before the proposed 2D seismic surveys would be conducted. The surveys will start after all the ice melts, usually near mid-July. The Point Hope bowhead whale hunt occurs from March to June. Whaling camps are established on the ice edge south and southeast of Point Hope, 10 to 11 km (6 to 7 mi) offshore. Due to ice conditions, the Point Hope hunt will likely be completed prior to commencement of the surveys. In the fall, whaling activities occur to the east of Point Barrow in the Beaufort Sea, while the proposed survey activities would be in the west of Point Barrow in the Chukchi Sea.

(2) Beluga Whales

Belugas typically do not represent a large proportion of the subsistence harvests by weight in the communities of Wainwright and Barrow. Barrow residents hunt beluga in the spring normally after the bowhead hunt) in leads between Point Barrow and Skull Cliffs in the Chukchi Sea primarily in April–June, and later in the summer (July–August) on both sides of the barrier island in Elson Lagoon/Beaufort Sea (MMS 2008), but harvest rates indicate the hunts are not frequent. Wainwright residents hunt beluga in April–June in the spring lead system, but this hunt typically occurs only if there are no bowheads in the area. Communal hunts for beluga are conducted along the coastal lagoon system later in July–August. Between 2005 and 2009, the annual beluga subsistence take was 94 whales (Allen and Angliss 2012) among both Wainwright and Barrow.

Belugas typically represent a much greater proportion of the subsistence harvest in Point Lay and Point Hope. Point Lay's primary beluga hunt occurs from mid-June through mid-July, but can sometimes continue into August if early success is not sufficient. Belugas are harvested in coastal waters near these villages, generally within a few miles from shore. However, the southern extent of TGS' proposed surveys is over 88 m to the north of Point Lay, and much farther away from Point Hope. Therefore NMFS considers that the surveys would have no or negligible effect on beluga hunts.

(3) Seals

Seals are an important subsistence resource and ringed seals make up the bulk of the seal harvest. Most ringed and bearded seals are harvested in the winter or in the spring before TGS' 2013 activities would commence, but some harvest continues during open water and could possibly be affected by TGS' planned activities. Spotted seals are also harvested during the summer. Most seals are harvested in coastal waters, with available maps of recent and past subsistence use areas indicating seal harvests have occurred only within 30–40 mi (48–64 km) off the coastline. TGS does not plan to survey within 88 km (55 mi) of the coast, which means that the proposed activities are not likely to have an impact on subsistence hunting for seals.

As stated earlier, the proposed seismic survey would take place between July and October. The proposed seismic survey activities would be conducted in far offshore waters of the Chukchi Sea and away from any subsistent activities. In addition, the timing of the survey activities that would be conducted between July and October would further avoid any spring hunting activities in Chukchi Sea villages. Therefore, due to the time and spatial separation of TGS' proposed 2D seismic surveys and the subsistent harvest by the local communities, it is anticipated to have no effects on spring harvesting and little or no effects on the occasional summer harvest of beluga whale, subsistence seal hunts (ringed and spotted seals are primarily harvested in winter while bearded seals are hunted during July–September in the Beaufort Sea), or the fall bowhead hunt.

In addition, TGS has developed and proposes to implement a number of mitigation measures (described in the next section) which include a proposed Marine Mammal Monitoring and Mitigation Plan (4MP), employment of subsistence advisors in the villages, and implementation of a Communications Plan (with operation of Communication Centers). TGS has also prepared a Plan of Cooperation (POC) under 50 CFR 216.104 Article 12 of the MMPA that addresses potential impacts on subsistent seal hunting activities.

Finally, to ensure that there will be no conflict from TGS' proposed open-water seismic surveys to subsistence activities, TGS stated that it will maintain communications with subsistence communities via the communication centers (Com and Call Centers) and signed the Conflict Avoidance Agreement (CAA) with Alaska whaling communities.

Proposed Mitigation

In order to issue an incidental take authorization under Section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable adverse impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses.

For the proposed TGS open-water marine 2D seismic surveys in the Chukchi Sea, TGS worked with NMFS and proposed the following mitigation measures to minimize the potential impacts to marine mammals in the project vicinity as a result of the marine seismic survey activities. The primary purpose of these mitigation measures is to detect marine mammals within, or about to enter designated exclusion zones and to initiate immediate shutdown or power down of the airgun(s), therefore it is very unlikely potential injury or TTS to marine mammals would occur, and Level B behavioral of marine mammals would be reduced to the lowest level practicable.

(1) Establishing Exclusion and Disturbance Zones

Under current NMFS guidelines, the ''exclusion zone'' for marine mammal exposure to impulse sources is customarily defined as the area within which received sound levels are ≥180 dB (rms) re 1 μPa for cetaceans and ≥190 dB (rms) re 1 μPa for pinnipeds. These safety criteria are based on an assumption that SPL received at levels lower than these will not injure these animals or impair their hearing abilities, but that at higher levels might have some such effects. Disturbance or behavioral effects to marine mammals from underwater sound may occur after exposure to sound at distances greater than the exclusion zones (Richarcdson *et al.* 1995). Currently, NMFS uses 160 dB (rms) re 1 μPa as the threshold for Level B behavioral harassment from impulses noise.

The acoustic source level of the proposed 3,280 in^3 seismic source array was predicted using JASCO's airgun array source model (AASM) based on data collected from three sites chosen in the project area by JASCO. Water depths at the three sites were 17, 40, and 100 m. JASCO applied its Marine Operations Noise Model (MONM) to estimate acoustic propagation of the proposed seismic source array and the associated distances to the 190, 180 and 160 dB (rms) re 1 μPa isopleths relative to standard NMFS mitigation and monitoring requirements for marine mammals. The resulting isopleths modeled for the 180 and 190 dB (rms) re 1 μPa exclusion zone distances for cetaceans and pinnipeds, respectively, differed with the three water depths. An additional 10 percent distance buffer was added by JASCO to these originally modeled distances to provide larger, more protective exclusion zone radii. The modeled exclusion zones and zones of influence are listed in Table 1.

These safety distances will be implemented at the commencement of 2013 airgun operations to establish marine mammal exclusion zones used for mitigation. TGS will conduct sound source measurements of the airgun array at the beginning of survey operations in 2013 to verify the size of the various marine mammal exclusion zones. The acoustic data will be analyzed as quickly as reasonably practicable in the field and used to verify and adjust the marine mammal exclusion zone distances. The mitigation measures to be implemented at the 190 and 180 dB (rms) sound levels will include power downs and shut downs as described below.

(2) Vessel Related Mitigation Measures

This proposed mitigation measures apply to all vessels that are part of the Chukchi Sea seismic survey activities, including the supporting vessel.

- Avoid concentrations or groups of whales by all vessels under the direction of TGS. Operators of vessels should, at all times, conduct their activities at the maximum distance possible from such concentrations of whales.
- Vessels in transit shall be operated at speeds necessary to ensure no physical contact with whales occurs. If any vessel approaches within 1.6 km (1 mi) of observed bowhead whales, except when providing emergency assistance to whalers or in other emergency situations, the vessel operator will take reasonable precautions to avoid potential interaction with the bowhead whales by taking one or more of the following actions, as appropriate:
  - Reducing vessel speed to less than 5 knots within 300 yards (900 feet or 274 m) of the whale(s);
  - Steering around the whale(s) if possible;
  - Operating the vessel(s) in such a way as to avoid separating members of a group of whales from other members of the group;
  - Operating the vessel(s) to avoid causing a whale to make multiple changes in direction; and
  - Checking the waters immediately adjacent to the vessel(s) to ensure that no whales will be injured when the propellers are engaged.
- When weather conditions require, such as when visibility drops, adjust vessel speed accordingly to avoid the likelihood of injury to whales.

(3) Mitigation Measures for Airgun Operations

The primary role for airgun mitigation during the seismic surveys is to monitor marine mammals near the airgun array during all daylight airgun operations and during any nighttime start-up of the airguns. During the seismic surveys PSOs will monitor the pre-established exclusion zones for the presence of marine mammals. When marine mammals are observed within, or about to enter, designated safety zones, PSOs have the authority to call for immediate power down (or shutdown) of airgun operations as required by the situation. A summary of the procedures associated with each mitigation measure is provided below.

Ramp Up Procedure

A ramp up of an airgun array provides a gradual increase in sound levels, and involves a step-wise increase in the number and total volume of airguns firing until the full volume is achieved. The purpose of a ramp up (or ''soft start'') is to ''warn'' cetaceans and pinnipeds in the vicinity of the airguns and to provide time for them to leave the area and thus avoid any potential injury or impairment of their hearing abilities.

During the proposed open-water survey program, the seismic operator will ramp up the airgun arrays slowly. Full ramp ups (i.e., from a cold start after a shut down, when no airguns have been firing) will begin by firing a single airgun in the array (i.e., the mitigation airgun). A full ramp up, after a shut down, will not begin until there has been a minimum of 30 min of observation of the safety zone by PSOs to assure that no marine mammals are present. The entire exclusion zone must be visible during the 30-minute lead-in to a full ramp up. If the entire exclusion zone is not visible, then ramp up from a cold start cannot begin. If a marine mammal(s) is sighted within the safety zone during the 30-minute watch prior to ramp up, ramp up will be delayed until the marine mammal(s) is sighted outside of the exclusion zone or the animal(s) is not sighted for at least 15–30 minutes: 15 minutes for small odontocetes (harbor porpoise) and pinnipeds, or 30 minutes for baleen whales and large odontocetes (including beluga and killer whales and narwhal).

Use of a Small-Volume Airgun During Turns and Transits

Throughout the seismic survey, particularly during turning movements, and short transits, TGS will employ the use of a small-volume airgun (i.e., 60 in^3 ''mitigation airgun'') to deter marine mammals from being within the immediate area of the seismic operations. The mitigation airgun would be operated at approximately one shot per minute and would not be operated for longer than three hours in duration (turns may last two to three hours for the proposed project) during daylight hours. In cases when the next start-up after the turn is expected to be during lowlight or low visibility, continuous operation of mitigation airgun is permitted.

During turns or brief transits (e.g., less than three hours) between seismic tracklines, one mitigation airgun will continue operating. The ramp-up procedure will still be followed when increasing the source levels from one airgun to the full airgun array. However, keeping one airgun firing will avoid the prohibition of a ''cold start'' during darkness or other periods of poor visibility. Through use of this approach, seismic surveys using the full array may resume without the 30 minute observation period of the full exclusion zone required for a ''cold start.'' PSOs will be on duty whenever the airguns are firing during daylight, during the 30 minute periods prior to ramp-ups.

Power-Down and Shut Down Procedures

A power down is the immediate reduction in the number of operating energy sources from all firing to some smaller number (e.g., single mitigation airgun). A shut down is the immediate cessation of firing of all energy sources. The array will be immediately powered down whenever a marine mammal is sighted approaching close to or within the applicable safety zone of the full array, but is outside the applicable safety zone of the single mitigation source. If a marine mammal is sighted within or about to enter the applicable safety zone of the single mitigation

airgun, the entire array will be shut down (i.e., no sources firing).

Poor Visibility Conditions

TGS plans to conduct 24-hour operations. PSOs will not be on duty during ongoing seismic operations during darkness, given the very limited effectiveness of visual observation at night (there will be no periods of darkness in the survey area until mid-August). The proposed provisions associated with operations at night or in periods of poor visibility include the following:

- If during foggy conditions, heavy snow or rain, or darkness (which may be encountered starting in late August), the full 180 dB exclusion zone is not visible, the airguns cannot commence a ramp-up procedure from a full shut-down.
- If one or more airguns have been operational before nightfall or before the onset of poor visibility conditions, they can remain operational throughout the night or poor visibility conditions. In this case ramp-up procedures can be initiated, even though the exclusion zone may not be visible, on the assumption that marine mammals will be alerted by the sounds from the single airgun and have moved away.

(4) Mitigation Measures for Subsistence Activities

Regulations at 50 CFR 216.104(a)(12) require IHA applicants for activities that take place in Arctic waters to provide a Plan of Cooperation (POC) or information that identifies what measures have been taken and/or will be taken to minimize adverse effects on the availability of marine mammals for subsistence purposes.

TGS has prepared a POC, which relies upon the Chukchi Sea Communication Plans to identify the measures that TGS has developed in consultation with North Slope subsistence communities and will implement during its planned 2013 activities to minimize any adverse effects on the availability of marine mammals for subsistence uses. The POC describes important subsistence activities near the proposed survey program and summarizes actions TGS has taken to inform subsistence communities of the proposed survey activities; and measures it will take to minimize adverse effects on marine mammals where proposed activities may affect the availability of a species or stock of marine mammals for arctic subsistence uses or near a traditional subsistence hunting area.

TGS began stakeholder engagement by introducing the project to the North Slope Borough (NSB) Planning Commission on October 25, 2012, and it also met with the NSB Planning Director and other Barrow leadership. In December 2012, TGS met with Chukchi Sea community leaders at the tribal, city, and corporate level in Barrow, Wainwright, Point Hope, Point Lay, and Kotzebue. TGS also introduced the project to the Alaska Eskimo Whaling Commission (AEWC) at their 4th Quarter Meeting on December 13–14, 2012, in Anchorage.

Community POC meetings were held in Barrow, Kotzebue, Point Hope, Point Lay, and Wainwright in January and February 2013. Finally, in February 2013, TGS participated the AEWC mini-convention and on Conflict Avoidance Agreement (CAA) discussion. A final POC that documents all consultations with community leaders and subsistence users was submitted to NMFS in May, 2013.

In addition, TGS signed a CAA with the Alaska whaling communities to further ensure that its proposed open-water seismic survey activities in the Chukchi Sea will not have unmitigable impacts to subsistence activities. NMFS has included appropriate measures identified in the CAA in the IHA.

Mitigation Conclusions

NMFS has carefully evaluated the applicant's proposed mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the means of effecting the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measure is expected to minimize adverse impacts to marine mammals; and
- The practicability of the measure for applicant implementation.

Based on our evaluation of the applicant's proposed measures, as well as other measures considered by NMFS, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, Section 101(a)(5)(D) of the MMPA states that NMFS must set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area.

I. Proposed Monitoring Measures

The monitoring plan proposed by TGS can be found in its Marine Mammal Monitoring and Mitigation Plan (4MP). The plan may be modified or supplemented based on comments or new information received from the public during the public comment period. A summary of the primary components of the plan follows.

Monitoring will provide information on the numbers of marine mammals potentially affected by the exploration operations and facilitate real time mitigation to prevent injury of marine mammals by industrial sounds or activities. These goals will be accomplished in the Chukchi Sea during 2013 by conducting vessel-based monitoring from both source vessel and supporting vessel and an acoustic monitoring program to using towed hydrophone array to document marine mammal presence and distribution in the vicinity of the survey area beyond visual observation distances.

Visual monitoring by Protected Species Observers (PSOs) during active marine survey operations, and periods when these surveys are not occurring, will provide information on the numbers of marine mammals potentially affected by these activities and facilitate real time mitigation to prevent impacts to marine mammals by industrial sounds or operations. Vessel-based PSOs onboard the survey vessel will record the numbers and species of marine mammals observed in the area and any observable reaction of marine mammals to the survey activities in the Chukchi Sea.

Real-time PAM would be conducted from the supporting vessel to complement the visual monitoring conducted by PSOs during the seismic surveys in the Chukchi Sea. Studies have indicated that towed PAM is a practical and successful application for augmenting visual surveys of low-frequency mysicetes, including blue and fin whales (Clark and Fristrup 1997). Passive acoustics methods, including towed hydrophone arrays, are most effective in remote areas, harsh environments (e.g. the arctic) and when visibility and/or sea conditions are poor,

or at nighttime or during low-light conditions when animals cannot be sighted easily. Surveys have collected more acoustic detections than visual observations while using towed PAM in the Arctic during an open-water seismic survey program conducted by Statoil in 2010 (McPherson *et al.* 2012). TGS states that the designed PAM system would provide the possibility of advanced real-time notification of vocalizing marine mammals that are not observed visually (or are observed after acoustic detection) and allow for mitigation actions (i.e., power-down, shut-down) to take place, if necessary.

Visual-Based Protected Species Observers (PSOs)

The visual-based marine mammal monitoring will be implemented by a team of experienced PSOs, including both biologists and Inupiat personnel. PSOs will be stationed aboard the survey and supporting vessels through the duration of the project. The vessel-based marine mammal monitoring will provide the basis for real-time mitigation measures as discussed in the Proposed Mitigation section. In addition, monitoring results of the vessel-based monitoring program will include the estimation of the number of ''takes'' as stipulated in the IHA.

(1) Protected Species Observers

Vessel-based monitoring for marine mammals will be done by trained PSOs throughout the period of survey activities. The observers will monitor the occurrence of marine mammals near the survey vessel during all daylight periods during operation, and during most daylight periods when operations are not occurring. PSO duties will include watching for and identifying marine mammals; recording their numbers, distances, and reactions to the survey operations; and documenting ''take by harassment''.

A sufficient number of PSOs will be required onboard the survey vessel to meet the following criteria:

- 100% monitoring coverage during all periods of survey operations in daylight;
- maximum of 4 consecutive hours on watch per PSO; and
- maximum of 12 hours of watch time per day per PSO.

PSO teams will consist of Inupiat observers and experienced field biologists. Each vessel will have an experienced field crew leader to supervise the PSO team. The total number of PSOs may decrease later in the season as the duration of daylight decreases.

(2) Observer Qualifications and Training

Crew leaders and most PSOs will be individuals with experience as observers during recent seismic, site clearance and shallow hazards, and other monitoring projects in Alaska or other offshore areas in recent years.

Biologist-observers will have previous marine mammal observation experience, and field crew leaders will be highly experienced with previous vessel-based marine mammal monitoring and mitigation projects. Resumes for those individuals will be provided to NMFS for review and acceptance of their qualifications. Inupiat observers will be experienced in the region and familiar with the marine mammals of the area. All observers will complete a NMFS-approved observer training course designed to familiarize individuals with monitoring and data collection procedures.

PSOs will complete a two or three-day training and refresher session on marine mammal monitoring, to be conducted shortly before the anticipated start of the 2013 open-water season. Any exceptions will have or receive equivalent experience or training. The training session(s) will be conducted by qualified marine mammalogists with extensive crew-leader experience during previous vessel-based seismic monitoring programs.

Marine Mammal Observer Protocol

The PSOs will watch for marine mammals from the best available vantage point on the survey vessels, typically the bridge. The PSOs will scan systematically with the unaided eye and 7 x 50 reticle binoculars, supplemented with 20 x 60 image-stabilized Zeiss Binoculars or Fujinon 25 x 150 ''Big-eye'' binoculars, and night-vision equipment when needed. Personnel on the bridge will assist the marine mammal observer(s) in watching for marine mammals.

The observer(s) aboard the survey and support vessels will give particular attention to the areas within the marine mammal exclusion zones around the source vessel. These zones are the maximum distances within which received levels may exceed 180 dB (rms) re 1 μPa (rms) for cetaceans, or 190 dB (rms) re 1 μPa for pinnipeds.

Distances to nearby marine mammals will be estimated with binoculars (Fujinon 7 x 50 binoculars) containing a reticle to measure the vertical angle of the line of sight to the animal relative to the horizon. Observers may use a laser rangefinder to test and improve their abilities for visually estimating distances to objects in the water.

When a marine mammal is seen approaching or within the exclusion zone applicable to that species, the marine survey crew will be notified immediately so that mitigation measures called for in the applicable authorization(s) can be implemented.

Night-vision equipment (Generation 3 binocular image intensifiers or equivalent units) will be available for use when/if needed. Past experience with night-vision devices (NVDs) in the Chukchi Sea and elsewhere has indicated that NVDs are not nearly as effective as visual observation during daylight hours (e.g., Harris et al. 1997, 1998; Moulton and Lawson 2002).

Field Data-Recording

The PSOs aboard the vessels will maintain a digital log of seismic surveys, noting the date and time of all changes in seismic activity (ramp-up, power-down, changes in the active seismic source, shutdowns, etc.) and any corresponding changes in monitoring radii in a project-customized Mysticetus™ observation software spreadsheet. In addition, PSOs will utilize this standardized format to record all marine mammal observations and mitigation actions (seismic source power-downs, shut-downs, and ramp-ups). Information collected during marine mammal observations will include the following:

- Vessel speed, position, and activity
- Date, time, and location of each marine mammal sighting
- Number of marine mammals observed, and group size, sex, and age categories
- Observer's name and contact information
- Weather, visibility, and ice conditions at the time of observation
- Estimated distance of marine mammals at closest approach
- Activity at the time of observation, including possible attractants present
- Animal behavior
- Description of the encounter
- Duration of encounter
- Mitigation action taken

Data will preferentially be recorded directly into handheld computers or as a back-up, transferred from hard-copy data sheets into an electronic database. A system for quality control and verification of data will be facilitated by the pre-season training, supervision by the lead PSOs, in-season data checks, and will be built into the Mysticetus™ software (i.e., Mysticetus™ will recognize and notify the operator if entered data are non-sensical). Computerized data validity checks will also be conducted, and the data will be managed in such a way that it is easily

summarized during and after the field program and transferred into statistical, graphical, or other programs for further processing. Mysticetus™ will be used to quickly and accurately summarize and display these data.

Passive Acoustic Monitoring

(1) Sound Source Measurements

Prior to or at the beginning of the seismic survey, sound levels will be measured as a function of distance and direction from the proposed seismic source array (full array and reduced to a single mitigation airgun). Results of the acoustic characterization and SSV will be used to empirically refine the modeled distance estimates of the pre-season 190 dB, 180 dB, and 160 dB isopleths. The refined SSV exclusion zones will be used for the remainder of the seismic survey. Distance estimates for the 120 dB isopleth will also be modeled. The results of the SSV will be submitted to NMFS within five days after completing the measurements, followed by a report in 14 days. A more detailed report will be provided to NMFS as part of the 90-day report following completion of the acoustic program.

(2) Real-Time Passive Acoustic Monitoring

TGS will conduct real-time passive acoustic monitoring using a towed hydrophone array from the support vessel. The towed hydrophone array system consists of two parts: The ''wet end'' and the ''dry end''. The wet end consists of the hydrophone array and tow cable that is towed behind the vessel. The dry end includes the analog-to-digital, computer processing, signal conditioning and filtering system used to process, record and analyze the acoustic data. Specific noise filters will be used to maximize the systems ability to detect low frequency bowhead whales. The towed hydrophone array will be deployed using a winch from the scout vessel. Details and specifications on the equipment will be determined at a later date once TGS has selected an acoustics contractor, as each contractor has different equipment specifications.

Localization of vocalizing animals will be accomplished using target motion analysis. With this method, it is possible with a single towed hydrophone array to obtain a localization to vocalizing animals given certain assumptions. Due to the linear alignment of hydrophones, there is a left/right ambiguity that cannot be resolved without turning the tow vessel. The left/right ambiguity, however, is not a critical concern for mitigation during the TGS 2D seismic survey because the exclusion zones are circular; therefore, the distance to the calling animal is the same on the right and left side of the vessel. Furthermore, unambiguous localization can be achieved in circumstances where the vessel towing the array can turn and the calling animals call multiple times or continuously.

To ensure the effectiveness of real-time PAM with a towed hydrophone array, the following requirements for PAM design and procedures will be required:

Lowering Interferences From Flow Noise

- Limit towing speeds to 4–6 knots. Reduce speed appropriately if bowhead whales are detected so that bearing can be obtained. If greater speeds are necessary, slow down every 20–30 minutes to listen for animal calls for at least 5–10 minutes.
- Maintain straight track-lines unless right/left ambiguity must be resolved (usually by turning 20–30 degrees at a time, then maintaining a straight course until good bearings can be obtained).
- Maintain a separation distance of at least several hundred meters (preferably more) from the seismic survey vessel.
- Design pre-amplifier filters that are 'tuned' to reduce low-frequency flow and vessel noise.
- If necessary, use a variable high-pass filter before digitizing the signals.

Monitoring Marine Mammal Occurrence Within 160 dB Isopleths

- Design a hydrophone array that is sensitive to frequencies of interest (e.g. marine mammal sounds) but attenuates (via filters) noise.
- Use a processing system that can further signal conditions (i.e. filter and match signal gains) to allow software to effectively estimate bearings and/or localize.
- Use software designed exclusively for monitoring, localizing and plotting marine mammal calls.
- Design the sampling software to optimize overlap between monitoring the 180 and 160 dB isopleths.
- Allow the survey vessel to deviate from designated track-lines by 25–30 degrees (for brief periods) so that left/right ambiguity can be resolved.

Increase Localization Capability

- Start with a simple hydrophone array, and if needed, add additional capabilities (or hydrophones) to supplement this system. For example, a 2-hydrophone array that can do TMA but with an additional array (or inline section) that can be added in front of the primary array would allow crossed-pair localization methods to be used.
- Use a processing and geographic display system that can accommodate at least the TMA localization method, but also, additional methods if needed.
- Provide at least 300 m of cable (for TMA methods), and up to 500 m if crossed-pair or hyperbolic localization methods will be used.

Monitoring Plan Peer Review

The MMPA requires that monitoring plans be independently peer reviewed ''where the proposed activity may affect the availability of a species or stock for taking for subsistence uses'' (16 U.S.C. 1371(a)(5)(D)(ii)(III)). Regarding this requirement, NMFS' implementing regulations state, ''Upon receipt of a complete monitoring plan, and at its discretion, [NMFS] will either submit the plan to members of a peer review panel for review or within 60 days of receipt of the proposed monitoring plan, schedule a workshop to review the plan'' (50 CFR 216.108(d)).

NMFS convened an independent peer review panel to review TGS' mitigation and monitoring plan in its IHA application for taking marine mammals incidental to the proposed open-water marine surveys and equipment recovery and maintenance in the Chukchi Sea during 2013. The panel met on January 8 and 9, 2013, and provided their final report to NMFS in March 2013. The full panel report can be viewed at: *http://www.nmfs.noaa.gov/pr/permits/incidental.htm#applications*.

NMFS provided the panel with TGS' monitoring and mitigation plan and asked the panel to address the following questions and issues for TGS' plan:

- Will the applicant's stated objectives effectively further the understanding of the impacts of their activities on marine mammals and otherwise accomplish the goals stated below? If not, how should the objectives be modified to better accomplish the goals above?
- Can the applicant achieve the stated objectives based on the methods described in the plan?
- Are there technical modifications to the proposed monitoring techniques and methodologies proposed by the applicant that should be considered to better accomplish their stated objectives?
- Are there techniques not proposed by the applicant (i.e., additional monitoring techniques or methodologies) that should be considered for inclusion in the applicant's monitoring program to better accomplish their stated objectives?

• What is the best way for an applicant to present their data and results (formatting, metrics, graphics, etc.) in the required reports that are to be submitted to NMFS (i.e., 90-day report and comprehensive report)?

The peer review panel report contains recommendations that the panel members felt were applicable to the TGS' monitoring plans. The panel agrees that the objective of vessel-based monitoring to implement mitigation measures to prevent or limit Level A takes is appropriate. In addition, at the time the panel reviewed the TGS' proposed marine mammal monitoring and mitigation plan, TGS only proposed vessel-based visual monitoring (but subsequently added PAM as described above). The panel was particularly concerned that there are considerable limitations to the ability of PSOs to monitor the full extent of the zones of influence, as these zones extend to as far as 15 km beyond the source. In addition, the panel pointed out that TGS did not specify how it planned to operate the scout vessel for marine mammal monitoring.

Specific recommendations provided by the peer review panel to enhance marine mammal monitoring, especially far distance monitoring beyond exclusion zones, include: (1) Implementing passive acoustic monitoring, with the bottom mounted passive acoustic recorders probably being the most appropriate method; (2) deploying a real-time, passive acoustic monitoring device that is linked by satellite (i.e., Iridium) phone; (3) collaborating with NMFS to use aerial survey data for assessing marine mammal distribution, relative abundance, behavior, and possible impacts relative to seismic surveys; (4) looking into possibility of using unmanned aerial systems to survey for marine mammals in offshore areas; and (5) utilizing new technologies, such as underwater vehicles, gliders, satellite monitoring, etc., to conduct far-field monitoring.

NMFS discussed extensively with TGS to improve the far-field marine mammal monitoring. As a result, upon further investigation and conversations with both JASCO and Bio-Waves by TGS, as well as further research into past Arctic marine mammal monitoring results conducted with towed-PAM, NMFS and TGS agree that utilizing a well-designed towed-PAM system would meet the need to provide enhanced marine mammal monitoring beyond exclusion zones, as well as using acoustic data for limited relative abundance and distribution analysis, and possibly limited insights on impacts to marine mammals.

NMFS also studied other PAM methodologies suggested by the peer-review panel. First, concerning deploying fixed bottom mounted recorders, TGS states that it has been in contact with other operators but was not able to find a collaborator to participate in long-term acoustic monitoring due to the short-term nature of the proposed survey. Regarding the real-time acoustic monitoring with fixed buoy, TGS stated that it conducted an evaluation of this option and discussed the possibility with the Cornell University's Bioacoustical Research Program concerning its real-time marine acoustic recording unit (MARU), but decided that the technology is still in the research and development stage. TGS also states that it did not consider the technology because the cost is more expensive than other PAM methods. TGS also discussed (with NMFS scientists) the possibility of using NMFS' aerial survey data for assessing marine mammal distribution, relative abundance, and possible impacts relative to seismic surveys. However, most of TGS' survey areas are outside NMFS aerial survey area, which makes it im possible to use these datasets for impact analyses. TGS also did a cost-benefit analysis of manned aerial surveys, and eliminated this as an option due to increased health and safety exposure risk, especially north of 72° N. TGS also investigated the possibility of using unmanned aerial vehicle (UAV) to survey for marine mammals in offshore areas, however, it has also turned out not to be feasible due to the fact that the approach is currently awaiting an FAA permit to operate in the Arctic, and this permit could not be guaranteed to be obtained in time for the TGS monitoring effort. TGS states that it did consider new technologies, but did not feel that they could justify the expense of testing techniques with unknown capabilities in the Arctic environment.

In addition, the panel also recommends that TGS collaborate with other organizations operating in the Chukchi Sea and share visual and acoustic data to improve understanding of impacts from single and multiple operations and efficacy of mitigation measures. Accordingly, TGS plans to share these data via the OBIS–SEAMAP Web site entertaining all appropriate data-sharing agreements, including data obtained using towed PAM.

II. Reporting Measures

Sound Source Verification Reports

A report on the preliminary results of the sound source verification measurements, including the measured 190, 180, and 160 dB (rms) radii of the airgun sources, would be submitted within 14 days after collection of those measurements at the start of the field season. This report will specify the distances of the exclusion zones that were adopted for the survey.

Field Reports

Throughout the survey program, PSOs will prepare a report each day or at such other intervals, summarizing the recent results of the monitoring program. The reports will summarize the species and numbers of marine mammals sighted. These reports will be provided to NMFS and to the survey operators.

Technical Reports

The results of TGS' 2013 vessel-based monitoring, including estimates of ''take'' by harassment, would be presented in the ''90-day'' and Final Technical reports, if the IHA is issued for the proposed open-water 2D seismic surveys. The Technical Reports should be submitted to NMFS within 90 days after the end of the seismic survey. The Technical Reports will include:

(a) summaries of monitoring effort (e.g., total hours, total distances, and marine mammal distribution through the study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals);

(b) analyses of the effects of various factors influencing detectability of marine mammals (e.g., sea state, number of observers, and fog/glare);

(c) species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover;

(d) To better assess impacts to marine mammals, data analysis should be separated into periods when a seismic airgun array (or a single mitigation airgun) is operating and when it is not. Final and comprehensive reports to NMFS should summarize and plot:

• Data for periods when a seismic array is active and when it is not; and

• The respective predicted received sound conditions over fairly large areas (tens of km) around operations;

(e) sighting rates of marine mammals during periods with and without airgun activities (and other variables that could affect detectability), such as:

• initial sighting distances versus airgun activity state;

• closest point of approach versus airgun activity state;
• observed behaviors and types of movements versus airgun activity state;
• numbers of sightings/individuals seen versus airgun activity state;
• distribution around the survey vessel versus airgun activity state; and
• estimates of take by harassment;

(f) Reported results from all hypothesis tests should include estimates of the associated statistical power when practicable;

(g) Estimate and report uncertainty in all take estimates. Uncertainty could be expressed by the presentation of confidence limits, a minimum-maximum, posterior probability distribution, etc.; the exact approach would be selected based on the sampling method and data available;

(h) The report should clearly compare authorized takes to the level of actual estimated takes; and

(i) Methodology used to estimate marine mammal takes and relative abundance on towed PAM.

Notification of Injured or Dead Marine Mammals

In addition, NMFS would require TGS to notify NMFS' Office of Protected Resources and NMFS' Stranding Network within 48 hours of sighting an injured or dead marine mammal in the vicinity of marine survey operations. TGS shall provide NMFS with the species or description of the animal(s), the condition of the animal(s) (including carcass condition if the animal is dead), location, time of first discovery, observed behaviors (if alive), and photo or video (if available).

In the event that an injured or dead marine mammal is found by TGS that is not in the vicinity of the proposed open-water marine survey program, TGS would report the same information as listed above as soon as operationally feasible to NMFS.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, the MMPA defines ''harassment'' as: any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B behavioral harassment is anticipated as a result of the proposed open water marine survey program. Anticipated impacts to marine mammals are associated with noise propagation from the survey airgun(s) used in the seismic surveys.

The full suite of potential impacts to marine mammals was described in detail in the ''Potential Effects of the Specified Activity on Marine Mammals'' section found earlier in this document. The potential effects of sound from the proposed open water marine survey programs might include one or more of the following: masking of natural sounds; behavioral disturbance; non-auditory physical effects; and, at least in theory, temporary or permanent hearing impairment (Richardson *et al.* 1995). As discussed earlier in this document, the most common impact will likely be from behavioral disturbance, including avoidance of the ensonified area or changes in speed, direction, and/or diving profile of the animal. For reasons discussed previously in this document, hearing impairment (TTS and PTS) is highly unlikely to occur based on the proposed mitigation and monitoring measures that would preclude marine mammals from being exposed to noise levels high enough to cause hearing impairment.

For impulse sounds, such as those produced by airgun(s) used in the 2D seismic surveys, NMFS uses the 160 dB (rms) re 1 μPa isopleth to indicate the onset of Level B harassment. TGS provided calculations for the 160-dB isopleths produced by the proposed seismic surveys and then used those isopleths to estimate takes by harassment. NMFS used the calculations to make the necessary MMPA preliminary findings. TGS provided a full description of the methodology used to estimate takes by harassment in its IHA application, which is also provided in the following sections.

Basis for Estimating ''Take by Harassment''

The estimated takes by harassment is calculated in this section by multiplying the expected densities of marine mammals that may occur near the planned activities by the area of water likely to be exposed to impulse sound levels of ≥160 dB (rms) re 1 μPa.

Marine mammal occurrence near the operation is likely to vary by season and habitat, mostly related to the presence or absence of sea ice. Although current NMFS' noise exposure standards state that Level B harassment occurs at exposure levels ≥160 dB (rms) re 1 μPa by impulse sources, there is no evidence that avoidance at these received sound levels would have significant biological effects on individual animals. Any changes in behavior caused by sounds at or near the specified received levels would likely fall within the normal variation in such activities that would occur in the absence of the planned operations. However, these received levels are currently used to set the threshold for Level B behavioral harassment.

Marine Mammal Density Estimates

The first step in estimating the number of marine mammals that might be ''taken by harassment'' was to conduct a review of available data on density estimates for the marine mammal species occurring in the project vicinity and adjacent areas of the Chukchi Sea. While several densities are available for U.S. waters in the Chukchi Sea, no reliable estimates are known for U.S. waters north of 72° N. Furthermore, no systematic surveys are known for the western half of the proposed project area in international waters.

Therefore, densities used to estimate exposures were based on two recent IHA applications and three 90-day reports to NMFS summarizing results of field monitoring surveys. These project areas overlapped the proposed TGS project area to at least some extent as well as TGS' proposed July–October seismic operations period. A map showing the boundaries of these survey areas relative to TGS' proposed seismic line locations is provided in Figure 2 of TGS' IHA application. The surveys consisted of the (1) two Statoil 90-day reports from the northern Chukchi Sea (Blees *et al.* 2010; Hartin *et al.* 2011), (2) UAGI's IHA (LGL 2011) and 90-day report (Cameron *et al.* 2012), and (3) Shell 2012 IHA (Shell 2011). These data are considered the ''best available'' density estimates and occurrence data currently available for the project area.

All recent density estimates for four different project areas overlapping the TGS project area based on the observed or derived densities reported in other studies (Blees *et al.* 2010; Hartin *et al.* 2011; LGL 2011; Shell 2011; Cameron *et al.* 2012) and are shown in Table 3 of TGS' IHA application. Note that only the Cameron *et al.* (2012) survey occurred north of 72° N in U.S. waters and international waters partially overlapping the TGS project area. Sightings providing data on observed densities were available for the following six species: the bowhead, gray and beluga whale, and the bearded, ringed and spotted seal. The remaining other six species occur so rarely in the project area vicinity that reliable densities are not available for them and/or no sightings were made during the

reported surveys: the humpback, minke, fin, and killer whales, the harbor porpoise, and the ribbon seal (Blees *et al.* 2010; Hartin *et al.* 2011; Cameron *et al.* 2012). Thus, certain fractional numbers were assigned to them based on those reported for other IHAs overlapping the proposed TGS project area, to address the rare chance of an encounter (Blees *et al.* 2010; Hartin *et al.* 2011; LGL 2011; Shell 2011; Cameron *et al.* 2012).

Adjustment Factors Applied To Provide Lower and Upper Estimates of Density

A number of habitat parameters have been shown to influence the distribution of marine mammal species occurring in the TGS project area. These parameters were applied to adjust the density of species accordingly, as done by other applicants in previous IHA applications (e.g., Blees *et al.* 2010; Hartin *et al.* 2011; LGL 2011; Shell 2011, Cameron *et al.* 2012). These included (1) open water (i.e., ice-free) vs. ice-edge margin (higher densities of pinnipeds and beluga whales occur near and/or within the ice margin), (2) summer (July–August) vs. fall (September–October), (3) water depth (>200 vs. <200 m deep), and (4) likelihood of occurrence above or below 72° N. Open-water densities were used if available because TGS operations must completely avoid ice to be able to safely and effectively conduct operations.

Densities (Table 3 in TGS' IHA application) used to estimate and calculate the number of exposures to TGS' seismic impulse sound levels ≥160 dB (rms) re 1μ Pa were obtained by (1) averaging the densities from the four previous studies by summer (July–August), fall (September–October), and summer-fall, and then (2) multiplying the resulting averaged densities by adjustment factors for water depth (shallower or deeper than 200 m) and expected occurrence in waters north or south of 72° N. Notably, TGS plans to operate above 72° N for about half (32 days) of the total 45- 60-day period in US Federal waters (35 days of which would involve seismic operations), and for all operations in international waters, up to 33 days. These northern waters above 72° N would be accessed sometime between about mid-September and 15 October (when waters are ice-free).

Because few data were available for most of the survey area, particularly north of 72° N and west of Barrow, it is not known how closely the applied average densities reflect the actual densities that will be encountered during the proposed TGS seismic survey. Thus, lower and upper adjustment factors (Table 4 in TGS' IHA application) were multiplied by the averaged densities to provide a range of density estimates. The latter adjustment was incorporated into a formula to estimate exposures to seismic sounds. The ''lower adjustment factor'' does not apply adjustment factors to densities north of 72° N for the bowhead and beluga whale and the ringed and bearded seal. In contrast, the ''upper adjustment factor'' applies factors to account for the expected lower density of marine mammal species north of 72° N. Adjustment factors differed by species and were based on (1) the reported distribution and occurrence of each species in these waters, and (2) factors applied by ION (LGL 2012) for their 2012 IHA application for the fall period of Oct–Dec 2012 that overlapped the fall period (mid-to-late September–October) and north-easternmost region that TGS expects to operate in international waters during fall.

TGS applied these density data and factors previously applied in an IHA issued to ION to account for expected lower densities above 72° N where waters are predominantly >1,000 m deep. The upper-adjusted (i.e., lower) density estimate was calculated by multiplying reported fall densities for more southern Chukchi waters as follows: (1) by a factor of 0.0 for fin, humpback, minke and killer whales, and harbor porpoise and ribbon and spotted seals as they are not expected in waters above 72° N and thus were assumed not to occur there; (2) by an adjustment factor of 0.01 for gray whales (since the northernmost boundary of their distribution is near 72° N and they are thus considered highly unlikely to occur above 72° N; (3) by a factor of 0.1 for bowhead whales as the area is outside the main migration corridor, and (4) by a factor of 0.1 for beluga whales and bearded and ringed seals as they are closely associated with ice, and thus considered less likely to occur in ice-free waters needed to conduct the TGS seismic operations.

A similar 0.1 adjustment factor was applied in the ION IHA (LGL 2012) for species where the seismic survey area was on the edge of that species' range at the given time of year. ION's adjustment factor of 0.1 was used for TGS density estimates because TGS proposes to be well north and west of ION's westernmost 2012 survey lines no earlier than 15–30 September through 31 October 2013. In comparison, ION proposed their program for 1 October through mid-December, and their actual program occurred in the Chukchi and Beaufort Seas from 20 October–9 November, 2012. These periods overlap the majority of the period that TGS is expected to be operating at or near the westernmost seismic lines (no earlier than 15–30 September through October) between 73°–76° N and 160° W to 160° E. Thus, ION's ''late season'' period coincides with TGS' proposed late fall season both in time and space relative to waters above 72° N.

The upper density estimates consisted of the averaged fall densities for more southern Chukchi waters by only (1) a smaller adjustment factor of 0.20 for gray whales (Table 4 of TGS' IHA application), and (2) by the same factor of 0.0 for fin, humpback, minke and killer whales, and harbor porpoise and ribbon and spotted seals as described above.

Additional Rationale for Adjusting Densities North of 72° N

- No whale sightings have been reported in waters north of 72° N during the few recent vessel-based surveys conducted there that overlapped the southern or eastern part of the proposed TGS project area and season (Blees *et al.* 2010; Hartin *et al.* 2011; Cameron *et al.* 2012).
- The main fall migration corridor for bowheads reportedly occurs south of 72° N (Quakenbush *et al.* 2010). However, satellite-tagging studies indicate that at least some individual bowheads migrate generally west/southwest across the project area in waters above 72° N and west of Barrow during the fall migration from September–November (Quakenbush 2007; LGL 2011; Quakenbush *et al.* 2012).
- The reported gray whale distribution in the Chukchi Sea normally does not extend much north of 72° N during summer/fall (Jefferson *et al.* 2008). This northernmost peripheral boundary area is thus expected to have very low gray whale densities. Furthermore, most gray whales will have migrated south of the project area by fall (Rice and Wolman 1971; Allen and Angliss 2012).

Exposure Calculation Methods

The approach used to calculate the estimated number of individuals of each marine mammal species potentially exposed to received levels of seismic impulse sound levels ≥160 dB (rms) re 1 μPa during the proposed seismic project is described below.

1. The area of water (in km^2) ensonified to ≥160 dB (rms) re 1 μPa around the operating seismic source array on seismic lines as well as turns and transits between seismic lines was calculated for U.S. and international waters for waters shallower and deeper

than 200 m, and for waters north and south of 72° N (Table 2). It was assumed for purposes of this estimation that the full seismic source array would be used during all seismic lines and during the 1-km run-in and 5-km run-out between seismic lines. In addition, it was assumed that a single 60 in³ airgun would be used during turns and transits between seismic lines. Ensonified waters were calculated as follows.

2. A buffer was applied on both sides of the planned survey tracklines equivalent to the distances modeled for the proposed 3,280 in³ seismic source array by JASCO in 2010 at three locations in the project area (Zykov *et al.* 2013). The buffer width corresponding to this 160 (rms) dB re 1 μPa isopleth varied with three water depth categories. Thus, survey tracklines located over waters 17–40 m deep were buffered by 8.5 km, those over waters 41–100 m deep were buffered by 9.9 km, and those over water depths of >100 m were buffered by 15 km.

TABLE 2—ESTIMATED AREA (KM²) ENSONIFIED TO >160 DB (RMS) RE 1 μPA BY SEISMIC IMPULSES ALONG TGS' 2013 PROPOSED SEISMIC LINES AND TURNS IN U.S. AND INTERNATIONAL WATERS OF THE CHUKCHI SEA. ENSONIFIED AREAS ASSUMED THAT THE FULL 3,280 IN³ ARRAY OPERATED CONTINUOUSLY ON SURVEY LINES AND THAT THE SINGLE MITIGATION AIRGUN (60 IN³) OPERATED CONTINUOUSLY ON TURNS (AND TRANSITS) BETWEEN SURVEY LINES

	Above 72° N		Below 72° N		Water depth < 200 m		Water depth > 200 m		All lines	All turns	All lines and turns
	Total lines area (km²)	Turns area (km²)	Total lines area (km²)	Turns area (km²)	Total lines area (km²)	Turns area (km²)	Total lines area (km²)	Turns area (km²)	Total lines area (km²)	Total turns area (km²)	Total ensonified area (km²)
US	65477	1294	72974	1442	114858	2770	23594	466	138452	2736	141188
International	115135	4200	0	0	45954	1676	69181	2524	115135	4200	119335
Total	180612	5494	72974	1442	160812	3946	92775	2990	253586	6936	260522

3. A smaller buffer was applied to both sides of turn lines between seismic lines equivalent to the measured distance to the 160 dB (rms) re 1 μPa isopleth of a single 60 in³ array as measured by JASCO. The associated area in km² was calculated using Mysticetus™ software. Mysticetus™ identified water depths at 100-m intervals along the survey trackline using bathymetric data. At each 100-m interval, Mysticetus™ applied one of the three aforementioned 160 dB (rms) re 1 μPa radius isopleths corresponding to that water depth. Overlapping areas were treated separately. The resulting World Geodetic System (WGS) 84 polygons were re-projected into North Pole Stereographic coordinates and the total area was calculated.

4. Averaged densities of marine mammals (Table 3 in TGS' IHA application) were adjusted as applicable (Table 4 in TGS' IHA application) then multiplied by the area predicted to be ensonified to ≥160 dB (rms) re 1 μPa. The procedure is outlined below.

- Because TGS expects to conduct seismic lines in U.S. Federal waters sometime between mid-July and mid-September in late summer and early fall, the proportion of U.S. Federal waters ensonified to >160 dB (rms) re 1 μPa was multiplied by the average of summer and fall densities reported from other studies (Table 3 in TGS' IHA application).
- Because TGS expects to conduct seismic lines in international waters starting in fall from mid-to-late September through October, the proportion of international waters ensonified to >160 dB (rms) re 1 μPa was multiplied by the average of fall densities reported from other studies (based nearly exclusively on surveys south of 72° N since it is considered the best and only systematic data available for the region).
- The proportions of ensonified waters north and south of 72° N were also calculated for U.S. and international waters. Species-specific average summer-fall and fall densities associated with these depth categories were multiplied by the corresponding proportion and season.
- In addition, the proportions of ensonified waters where water depth along the seismic line was <200 m deep or >200 m deep were calculated. Species-specific average summer-fall and fall densities associated with these depth categories were multiplied by the corresponding proportion and season.
- Reported fall density estimates for gray, bowhead and beluga whales, and bearded and ringed seals were adjusted for ice-free waters N of 72° N by multiplying reported fall densities for more southern Chukchi waters by low and high adjustment factors described above to provide a range of potential exposures.

In a summary, estimated species exposures are calculated by multiplying seasonally (summer vs. fall) and spatially (above vs. below 72° N at various water depths) marine mammal density by the total ensonified areas with received levels higher than 160 dB re 1μPa (rms).

Potential Number of ''Take by Harassment''

As stated earlier, the estimates of potential Level B takes of marine mammals by noise exposure are based on a consideration of the number of marine mammals that might be present during operations in the Chukchi Sea and the anticipated area exposed to those sound pressure levels (SPLs) above 160 dB re 1 μPa for impulse sources (seismic airgun during 2D seismic surveys).

Some of the animals estimated to be exposed, particularly migrating bowhead whales, might show avoidance reactions before being exposed to sounds at the specified threshold levels. Thus, these calculations actually estimate the number of individuals potentially exposed to the specified sounds levels that would occur if there were no avoidance of the area ensonified to that level.

Numbers of marine mammals that might be present and potentially taken are summarized in Table 3 based on calculation described above.

TABLE 3—ESTIMATES OF THE POSSIBLE MAXIMUM NUMBERS OF MARINE MAMMALS TAKEN BY LEVEL B HARASSMENT (EXPOSED TO ≥160 dB FROM AIRGUN SOUND) DURING TGS' PROPOSED 2D SEISMIC SURVEY IN THE CHUKCHI SEA, JULY–OCTOBER 2013

Species	Level B takes	Percent population
Bowhead whale	794	7.53
Gray whale	1,363	7.13
Fin whale	5	0.09
Humpback whale	5	0.53
Minke whale	5	0.62
Beluga whale	412	11.11
Killer whale	5	1.59
Harbor porpoise	36	0.07
Ringed seal	30,000	14.36
Bearded seal	6000	0.84
Spotted seal	500	0.84
Ribbon seal	100	0.20

Estimated Take Conclusions

Effects on marine mammals are generally expected to be restricted to avoidance of the area around the planned activities and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment''.

Cetaceans—The take calculation estimates suggest a total of 794 bowhead whales may be exposed to sounds at or above 160 dB (rms) re 1 μPa (Table 3). This number is approximately 7.53% of the Bering–Chukchi–Beaufort (BCB) population of 10,545 assessed in 2001 (Allen and Angliss 2011) and is assuming to be increasing at an annual growth rate of 3.4% (Zeh and Punt 2005), which is supported by a 2004 population estimate of 12,631 by Koski *et al.* (2010). The total estimated number of gray and beluga whales that may be exposed to sounds from the activities ranges up to 1,363 and 412, respectively (Table 3). Fewer harbor porpoises are likely to be exposed to sounds during the activities. The small numbers of other whale species that may occur in the Chukchi Sea are unlikely to be present around the planned operations but chance encounters may occur. The few individuals would represent a very small proportion of their respective populations.

Pinnipeds—Ringed seal is by far the most abundant species expected to be encountered during the planned operations. The best estimate of the numbers of ringed seals exposed to sounds at the specified received levels during the planned activities is 30,000, which represent up to 14.36% of the Alaska population. Fewer individuals of other pinniped species are estimated to be exposed to sounds at Level B behavioral harassment level, also representing small proportions of their populations.

Negligible Impact and Small Numbers Analysis and Preliminary Determination

As a preliminary matter, we typically include our negligible impact and small numbers analysis and determination under the same section heading of our **Federal Register** Notices. Despite co-locating these terms, we acknowledge that negligible impact and small numbers are distinct standards under the MMPA and treat them as such. The analysis presented below does not conflate the two standards; instead, each has been considered independently and we have applied the relevant factors to inform our negligible impact and small numbers determinations.

NMFS has defined ''negligible impact'' in 50 CFR 216.103 as ''. . . an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.'' In making a negligible impact determination, NMFS considers a variety of factors, including but not limited to: (1) The number of anticipated mortalities; (2) the number and nature of anticipated injuries; (3) the number, nature, intensity, and duration of Level B harassment; and (4) the context in which the takes occur.

No injuries or mortalities are anticipated to occur as a result of TGS' proposed 2013 open-water 2D seismic surveys in the Chukchi Sea, and none are proposed to be authorized. Additionally, animals in the area are not expected to incur hearing impairment (i.e., TTS or PTS) or non-auditory physiological effects. Takes will be limited to Level B behavioral harassment. Although it is possible that some individuals of marine mammals may be exposed to sounds from marine survey activities more than once, the expanse of these multi-exposures are expected to be less extensive since both the animals and the survey vessels will be moving constantly in and out of the survey areas.

Most of the bowhead whales encountered will likely show overt disturbance (avoidance) only if they receive airgun sounds with levels ≥ 160 dB re 1 μPa. Odontocete reactions to seismic airgun pulses are usually assumed to be limited to shorter distances from the airgun(s) than are those of mysticetes, probably in part because odontocete low-frequency hearing is assumed to be less sensitive than that of mysticetes. However, at least when in the Canadian Beaufort Sea in summer, belugas appear to be fairly responsive to seismic energy, with few being sighted within 6–12 mi (10–20 km) of seismic vessels during aerial surveys (Miller *et al.* 2005). Belugas will likely occur in small numbers in the Chukchi Sea during the survey period and few will likely be affected by the survey activity.

As noted, elevated background noise level from the seismic airgun reverberant field could cause acoustic masking to marine mammals and reduce their communication space. However, even though the decay of the signal is extended, the fact that pulses are separated by approximately 10 seconds means that overall received levels at distance are expected to be much lower, thus resulting in less acoustic masking.

Taking into account the mitigation measures that are planned, effects on marine mammals are generally expected to be restricted to avoidance of a limited area around TGS' proposed open-water activities and short-term changes in behavior, falling within the MMPA definition of ''Level B harassment''. The many reported cases of apparent tolerance by cetaceans of seismic exploration, vessel traffic, and some other human activities show that co-existence is possible. Mitigation measures such as controlled vessel speed, dedicated marine mammal observers, non-pursuit, and shut downs or power downs when marine mammals are seen within defined ranges will further reduce short-term reactions and minimize any effects on hearing sensitivity. In all cases, the effects are expected to be short-term, with no lasting biological consequence.

Of the thirteen marine mammal species likely to occur in the proposed marine survey area, bowhead, fin, and humpback whales and ringed and bearded seals are listed as endangered or threatened under the ESA. These species are also designated as ''depleted'' under the MMPA. Despite these designations, the BCB stock of bowheads has been increasing at a rate of 3.4 percent annually for nearly a decade (Allen and Angliss 2010). Additionally, during the 2001 census, 121 calves were counted, which was the highest yet recorded. The calf count provides corroborating evidence for a healthy and increasing population (Allen and Angliss 2010). The occurrence of fin and humpback whales in the proposed marine survey areas is considered very rare. There is no critical habitat designated in the U.S. Arctic for the bowhead, fin, and humpback whales. The Alaska stock of bearded

seals, part of the Beringia distinct population segment (DPS), and the Arctic stock of ringed seals, have recently been listed by NMFS as threatened under the ESA. None of the other species that may occur in the project area are listed as threatened or endangered under the ESA or designated as depleted under the MMPA.

Potential impacts to marine mammal habitat were discussed previously in this document (see the ''Anticipated Effects on Habitat'' section). Although some disturbance is possible to food sources of marine mammals, the impacts are anticipated to be minor enough as to not affect rates of recruitment or survival of marine mammals in the area. Based on the vast size of the Arctic Ocean where feeding by marine mammals occurs versus the localized area of the marine survey activities, any missed feeding opportunities in the direct project area would be minor based on the fact that other feeding areas exist elsewhere.

The estimated takes proposed to be authorized represent 11.11% of the Eastern Chukchi Sea population of approximately 3,710 beluga whales, 1.59% of Aleutian Island and Bering Sea stock of approximately 314 killer whales, 0.07% of Bering Sea stock of approximately 48,215 harbor porpoises, 7.13% of the Eastern North Pacific stock of approximately 19,126 gray whales, 7.53% of the Bering-Chukchi-Beaufort population of 10,545 bowhead whales, 0.53% of the Western North Pacific stock of approximately 938 humpback whales, 0.09% of the Northeast Pacific stock of approximately 5,700 fin whales, and 0.62% of the Alaska stock of approximately 810 minke whales. The take estimates presented for ringed, bearded, spotted, and ribbon seals represent 14.36, 2.47, 0.84, and 0.20% of U.S. Arctic stocks of each species, respectively. The mitigation and monitoring measures (described previously in this document) proposed for inclusion in the IHA (if issued) are expected to reduce even further any potential disturbance to marine mammals.

In addition, no important feeding and reproductive areas are known in the vicinity of the TGS' proposed seismic surveys at the time the proposed surveys are to take place. No critical habitat of ESA-listed marine mammal species occurs in the Chukchi Sea.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the mitigation and monitoring measures, NMFS preliminarily finds that TGS' proposed 2013 open-water 2D seismic surveys in the Chukchi Sea may result in the incidental take of small numbers of marine mammals, by Level B harassment only, and that the total taking from the marine surveys will have a negligible impact on the affected species or stocks.

Unmitigable Adverse Impact Analysis and Preliminary Determination

NMFS has preliminarily determined that TGS' proposed 2013 open-water 2D seismic surveys in the Chukchi Sea will not have an unmitigable adverse impact on the availability of species or stocks for taking for subsistence uses. This preliminary determination is supported by information contained in this document and TGS' POC. TGS has adopted a spatial and temporal strategy for its Chukchi Sea open-water seismic surveys that should minimize impacts to subsistence hunters. Due to the timing of the project and the distance from the surrounding communities, it is anticipated to have no effects on spring harvesting and little or no effects on the occasional summer harvest of beluga whale, subsistence seal hunts (ringed and spotted seals are primarily harvested in winter while bearded seals are hunted during July–September in the Beaufort Sea), or the fall bowhead hunt.

In addition, based on the measures described in TGS' POC, the proposed mitigation and monitoring measures (described earlier in this document), and the project design itself, NMFS has determined preliminarily that there will not be an unmitigable adverse impact on subsistence uses from TGS' 2013 open-water 2D seismic surveys in the Chukchi Sea.

Proposed Incidental Harassment Authorization

This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

(1) This Authorization is valid from July 15, 2013, through October 31, 2013.

(2) This Authorization is valid only for activities associated with open-water 2D seismic surveys and related activities in the Chukchi Sea. The specific areas where TGS' surveys will be conducted are within the Chukchi Sea, Alaska, as shown in Figure 1 of TGS' IHA application.

(3)(a) The species authorized for incidental harassment takings, Level B harassment only, are: Beluga whales (*Delphinapterus leucas*); harbor porpoises (*Phocoena phocoena*); killer whales (*Orcinus orca*); bowhead whales (*Balaena mysticetus*); gray whales (*Eschrichtius robustus*); humpback whales (*Megaptera novaeangliae*); fin whales (*Balaenoptera physalus*); minke whales (*B. acutorostrata*); bearded seals (*Erignathus barbatus*); spotted seals (*Phoca largha*); ringed seals (*P. hispida*); and ribbon seals (*P. fasciata*).

(3)(b) The authorization for taking by harassment is limited to the following acoustic sources and from the following activities:

(i) 3,280 in^3 airgun arrays and other acoustic sources for 2D open-water seismic surveys; and

(ii) Vessel activities related to open-water seismic surveys listed in (i).

(3)(c) The taking of any marine mammal in a manner prohibited under this Authorization must be reported within 24 hours of the taking to the Alaska Regional Administrator (907–586–7221) or his designee in Anchorage (907–271–3023), National Marine Fisheries Service (NMFS) and the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, at (301) 427–8401, or his designee (301) 427–8418).

(4) The holder of this Authorization must notify the Chief of the Permits and Conservation Division, Office of Protected Resources, at least 48 hours prior to the start of collecting seismic data (unless constrained by the date of issuance of this Authorization in which case notification shall be made as soon as possible).

(5) Prohibitions

(a) The taking, by incidental harassment only, is limited to the species listed under condition 3(a) above and by the numbers listed in Table 1 (attached). The taking by Level A harassment, injury or death of these species or the taking by harassment, injury or death of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this Authorization.

(b) The taking of any marine mammal is prohibited whenever the required source vessel protected species observers (PSOs), required by condition 7(a)(i), are not onboard in conformance with condition 7(a)(i) of this Authorization.

(6) Mitigation

(a) Establishing Exclusion and Disturbance Zones:

(i) Establish and monitor with trained PSOs a preliminary exclusion zones for cetaceans surrounding the airgun array on the source vessel where the received level would be 180 dB (rms) re 1 μPa. For purposes of the field verification test, described in condition 7(e)(i), these radii are estimated to be 2,200, 2,500, and 2,400 m from the seismic source for

the 3,280 in³ airgun array in water depths of 17–40, 40–100, and >100 m, respectively. The 180-dB radius from the single 60 in³ airgun is estimated to be at 68 m from the source, regardless of water depth.

(ii) Establish and monitor with trained PSOs a preliminary exclusion zones for pinnipeds surrounding the airgun array on the source vessel where the received level would be 190 dB (rms) re 1 μPa. For purposes of the field verification test, described in condition 7(e)(i), these radii are estimated to be 930, 920, and 430 m from the seismic source for the 3,280 in³ airgun array in water depths of 17–40, 40–100, and >100 m, respectively. The 190-dB radius from the single 60 in³ airgun is estimated to be at 13 m from the source, regardless of water depth.

(iii) Establish a zone of influence (ZOIs) for cetaceans and pinnipeds surrounding the airgun array on the source vessel where the received level would be 160 dB (rms) re 1 μPa. For purposes of the field verification test described in condition 7(e)(i), these radii are estimated to be 8,500, 9,900, and 15,000 m from the seismic source for the 3,280 in³ airgun array in water depths of 17–40, 40–100, and >100 m, respectively. The 160-dB radius from the single 60 in³ airgun is estimated to be at 1,500 m from the source.

(iv) Immediately upon completion of data analysis of the field verification measurements required under condition 7(e)(i) below, the new 160-dB, 180-dB, and 190-dB marine mammal ZOIs and exclusion zones shall be established based on the sound source verification.

(b) Vessel Movement Mitigation:

(i) Avoid concentrations or groups of whales (2 or more individuals) by all vessels under the direction of TGS. Operators of support vessels should, at all times, conduct their activities at the maximum distance possible from such concentrations of whales.

(ii) Vessels in transit shall be operated at speeds necessary to ensure no physical contact with whales occurs. If any vessel approaches within 1.6 km (1 mi) of observed bowhead whales, except when providing emergency assistance to whalers or in other emergency situations, the vessel operator will take reasonable precautions to avoid potential interaction with the bowhead whales by taking one or more of the following actions, as appropriate:

(A) Reducing vessel speed to less than 5 knots within 300 yards (900 feet or 274 m) of the whale(s);

(B) Steering around the whale(s) if possible;

(C) Operating the vessel(s) in such a way as to avoid separating members of a group of whales from other members of the group;

(D) Operating the vessel(s) to avoid causing a whale to make multiple changes in direction; and

(E) Checking the waters immediately adjacent to the vessel(s) to ensure that no whales will be injured when the propellers are engaged.

(iii) When weather conditions require, such as when visibility drops, adjust vessel speed accordingly to avoid the likelihood of injury to whales.

(c) Mitigation Measures for Airgun Operations

(i) Ramp-up:

(A) A ramp up, following a complete shutdown of 10 minutes or more, can be applied if the exclusion zone has been free of marine mammals for a consecutive 30-minute period. The entire exclusion zone must have been visible during these 30 minutes. If the entire exclusion zone is not visible, then ramp up from a cold start cannot begin.

(B) If a marine mammal(s) is sighted within the exclusion zone during the 30-minute watch prior to ramp up, ramp up will be delayed until the marine mammal(s) is sighted outside of the exclusion zone or the animal(s) is not sighted for at least 15–30 minutes: 15 minutes for small odontocetes (harbor porpoise) and pinnipeds, or 30 minutes for baleen whales and large odontocetes (including beluga and killer whales and narwhal).

(C) If, for any reason, electrical power to the airgun array has been discontinued for a period of 10 minutes or more, ramp-up procedures shall be implemented. Only if the PSO watch has been suspended, a 30-minute clearance of the exclusion zone is required prior to commencing ramp-up. Discontinuation of airgun activity for less than 10 minutes does not require a ramp-up.

(D) The seismic operator and PSOs shall maintain records of the times when ramp-ups start and when the airgun arrays reach full power.

(ii) Power-down/Shutdown:

(A) The airgun array shall be immediately powered down whenever a marine mammal is sighted approaching close to or within the applicable exclusion zone of the full array, but is outside the applicable exclusion zone of the single mitigation airgun.

(B) If a marine mammal is already within the exclusion zone when first detected, the airguns shall be powered down immediately.

(C) Following a power-down, firing of the full airgun array shall not resume until the marine mammal has cleared the exclusion. The animal will be considered to have cleared the exclusion zone if it is visually observed to have left the exclusion zone of the full array, or has not been seen within the zone for 15 minutes (pinnipeds or small toothed whales) or 30 minutes (baleen whales or large toothed whales).

(D) If a marine mammal is sighted within or about to enter the 190 or 180 dB (rms) applicable exclusion zone of the single mitigation airgun, the airgun array shall be shutdown.

(E) Firing of the full airgun array or the mitigation gun shall not resume until the marine mammal has cleared the exclusion zone of the full array or mitigation gun, respectively. The animal will be considered to have cleared the exclusion zone as described above under ramp up procedures.

(iii) Poor Visibility Conditions:

(A) If during foggy conditions, heavy snow or rain, or darkness, the full 180 dB exclusion zone is not visible, the airguns cannot commence a ramp-up procedure from a full shut-down.

(B) If one or more airguns have been operational before nightfall or before the onset of poor visibility conditions, they can remain operational throughout the night or poor visibility conditions. In this case ramp-up procedures can be initiated, even though the exclusion zone may not be visible, on the assumption that marine mammals will be alerted by the sounds from the single airgun and have moved away.

(iv) Use of a Small-Volume Airgun during Turns and Transits

(A) Throughout the seismic survey, particularly during turning movements, and short transits, TGS will employ the use of a small-volume airgun (i.e., 60 in³ ''mitigation airgun'') to deter marine mammals from being within the immediate area of the seismic operations. The mitigation airgun would be operated at approximately one shot per minute and would not be operated for longer than three hours in duration (turns may last two to three hours for the proposed project) during daylight hours. In cases when the next start-up after the turn is expected to be during lowlight or low visibility, continuous operation of mitigation airgun is permitted.

(B) During turns or brief transits (e.g., less than three hours) between seismic tracklines, one mitigation airgun will continue operating. The ramp-up procedure will still be followed when increasing the source levels from one airgun to the full airgun array. However, keeping one airgun firing will avoid the prohibition of a ''cold start'' during darkness or other periods of poor visibility. Through the use of this approach, seismic surveys using the full array may resume without the 30

minute observation period of the full exclusion zone required for a ''cold start''. PSOs will be on duty whenever the airguns are firing during daylight, during the 30 minute periods prior to ramp-ups.

(d) Mitigation Measures for Subsistence Activities:

(i) For the purposes of reducing or eliminating conflicts between subsistence whaling activities and TGS' survey program, the holder of this Authorization will participate with other operators in the Communication and Call Centers (Com-Center) Program. The Com-Centers will be operated 24 hours/day during the 2013 fall subsistence bowhead whale hunt.

(ii) The appropriate Com-Center shall be notified if there is any significant change in plans.

(iii) Upon notification by a Com-Center operator of an at-sea emergency, the holder of this Authorization shall provide such assistance as necessary to prevent the loss of life, if conditions allow the holder of this Authorization to safely do so.

(7) Monitoring:

(a) Vessel-based Visual Monitoring:

(i) Vessel-based visual monitoring for marine mammals shall be conducted by NMFS-approved protected species observers (PSOs) throughout the period of survey activities.

(ii) PSOs shall be stationed aboard the seismic survey vessel and supporting vessel through the duration of the surveys.

(iii) A sufficient number of PSOs shall be onboard the survey vessel to meet the following criteria:

(A) 100% monitoring coverage during all periods of survey operations in daylight;

(B) maximum of 4 consecutive hours on watch per PSO; and

(C) maximum of 12 hours of watch time per day per PSO.

(iv) The vessel-based marine mammal monitoring shall provide the basis for real-time mitigation measures as described in (6)(c) above.

(v) Results of the vessel-based marine mammal monitoring shall be used to calculate the estimation of the number of ''takes'' from the marine surveys.

(b) Protected Species Observers and Training

(i) PSO teams shall consist of Inupiat observers and NMFS-approved field biologists.

(ii) Experienced field crew leaders shall supervise the PSO teams in the field. New PSOs shall be paired with experienced observers to avoid situations where lack of experience impairs the quality of observations.

(iii) Crew leaders and most other biologists serving as observers in 2013 shall be individuals with experience as observers during recent seismic or shallow hazards monitoring projects in Alaska, the Canadian Beaufort, or other offshore areas in recent years.

(iv) Resumes for PSO candidates shall be provided to NMFS for review and acceptance of their qualifications. Inupiat observers shall be experienced in the region and familiar with the marine mammals of the area.

(v) All observers shall complete a NMFS-approved observer training course designed to familiarize individuals with monitoring and data collection procedures. The training course shall be completed before the anticipated start of the 2013 open-water season. The training session(s) shall be conducted by qualified marine mammalogists with extensive crew-leader experience during previous vessel-based monitoring programs.

(vi) Training for both Alaska native PSOs and biologist PSOs shall be conducted at the same time in the same room. There shall not be separate training courses for the different PSOs.

(vii) Crew members should not be used as primary PSOs because they have other duties and generally do not have the same level of expertise, experience, or training as PSOs, but they could be stationed on the fantail of the vessel to observe the near field, especially the area around the airgun array and implement a power down or shutdown if a marine mammal enters the safety zone (or exclusion zone).

(viii) If crew members are to be used as PSOs, they shall go through some basic training consistent with the functions they will be asked to perform. The best approach would be for crew members and PSOs to go through the same training together.

(ix) PSOs shall be trained using visual aids (e.g., videos, photos), to help them identify the species that they are likely to encounter in the conditions under which the animals will likely be seen.

(x) TGS shall train its PSOs to follow a scanning schedule that consistently distributes scanning effort according to the purpose and need for observations. All PSOs should follow the same schedule to ensure consistency in their scanning efforts.

(xi) PSOs shall be trained in documenting the behaviors of marine mammals. PSOs should simply record the primary behavioral state (i.e., traveling, socializing, feeding, resting, approaching or moving away from vessels) and relative location of the observed marine mammals.

(c) Marine Mammal Observation Protocol

(i) PSOs shall watch for marine mammals from the best available vantage point on the survey vessels, typically the bridge.

(ii) Observations by the PSOs on marine mammal presence and activity shall begin a minimum of 30 minutes prior to the estimated time that the seismic source is to be turned on and/or ramped-up.

(iii) PSOs shall scan systematically with the unaided eye and 7 x 50 reticle binoculars, supplemented with 20 x 60 image-stabilized Zeiss Binoculars or Fujinon 25 x 150 ''Big-eye'' binoculars, and night-vision equipment when needed.

(iv) Personnel on the bridge shall assist the marine mammal observer(s) in watching for marine mammals.

(v) PSOs aboard the marine survey vessel shall give particular attention to the areas within the marine mammal exclusion zones around the source vessel, as noted in (6)(a)(i) and (ii). They shall avoid the tendency to spend too much time evaluating animal behavior or entering data on forms, both of which detract from their primary purpose of monitoring the exclusion zone.

(vi) Monitoring shall consist of recording of the following information:

(A) The species, group size, age/size/sex categories (if determinable), the general behavioral activity, heading (if consistent), bearing and distance from seismic vessel, sighting cue, behavioral pace, and apparent reaction of all marine mammals seen near the seismic vessel and/or its airgun array (e.g., none, avoidance, approach, paralleling, etc);

(B) the time, location, heading, speed, and activity of the vessel (shooting or not), along with sea state, visibility, cloud cover and sun glare at (I) any time a marine mammal is sighted (including pinnipeds hauled out on barrier islands), (II) at the start and end of each watch, and (III) during a watch (whenever there is a change in one or more variable);

(C) the identification of all vessels that are visible within 5 km of the seismic vessel whenever a marine mammal is sighted and the time observed;

(D) any identifiable marine mammal behavioral response (sighting data should be collected in a manner that will not detract from the PSO's ability to detect marine mammals);

(E) any adjustments made to operating procedures; and

(F) visibility during observation periods so that total estimates of take can be corrected accordingly.

(vii) Distances to nearby marine mammals will be estimated with binoculars (Fujinon 7 x 50 binoculars)

containing a reticle to measure the vertical angle of the line of sight to the animal relative to the horizon. Observers may use a laser rangefinder to test and improve their abilities for visually estimating distances to objects in the water.

(viii) PSOs shall understand the importance of classifying marine mammals as ''unknown'' or ''unidentified'' if they cannot identify the animals to species with confidence. In those cases, they shall note any information that might aid in the identification of the marine mammal sighted. For example, for an unidentified mysticete whale, the observers should record whether the animal had a dorsal fin.

(ix) Additional details about unidentified marine mammal sightings, such as ''blow only'', mysticete with (or without) a dorsal fin, ''seal splash'', etc., shall be recorded.

(x) When a marine mammal is seen approaching or within the exclusion zone applicable to that species, the marine survey crew shall be notified immediately so that mitigation measures described in (6) can be promptly implemented.

(xi) TGS shall use the best available technology to improve detection capability during periods of fog and other types of inclement weather. Such technology might include night-vision goggles or binoculars as well as other instruments that incorporate infrared technology.

(d) Field Data-Recording and Verification

(A) PSOs aboard the vessels shall maintain a digital log of seismic surveys, noting the date and time of all changes in seismic activity (ramp-up, power-down, changes in the active seismic source, shutdowns, etc.) and any corresponding changes in monitoring radii in a software spreadsheet.

(B) PSOs shall utilize standardized format to record all marine mammal observations and mitigation actions (seismic source power-downs, shut-downs, and ramp-ups).

(C) Information collected during marine mammal observations shall include the following:

(I) Vessel speed, position, and activity
(II) Date, time, and location of each marine mammal sighting
(III) Number of marine mammals observed, and group size, sex, and age categories
(IV) Observer's name and contact information
(V) Weather, visibility, and ice conditions at the time of observation
(VI) Estimated distance of marine mammals at closest approach
(VII) Activity at the time of observation, including possible attractants present
(VIII) Animal behavior
(IX) Description of the encounter
(X) Duration of encounter
(XI) Mitigation action taken

(D) Data shall be recorded directly into handheld computers or as a back-up, transferred from hard-copy data sheets into an electronic database.

(E) A system for quality control and verification of data shall be facilitated by the pre-season training, supervision by the lead PSOs, in-season data checks, and shall be built into the software.

(F) Computerized data validity checks shall also be conducted, and the data shall be managed in such a way that it is easily summarized during and after the field program and transferred into statistical, graphical, or other programs for further processing.

(e) Passive Acoustic Monitoring

(i) Sound Source Measurements: Using a hydrophone system, the holder of this Authorization is required to conduct sound source verification tests for seismic airgun array(s) that are involved in the open-water seismic surveys.

(A) Sound source verification shall consist of distances where broadside and endfire directions at which broadband received levels reach 190, 180, 170, and 160 dB (rms) re 1 μPa for the airgun array(s). The configurations of airgun arrays shall include at least the full array and the operation of a single source that will be used during power downs.

(B) The test results shall be reported to NMFS within 5 days of completing the test.

(ii) Real-time Passive Acoustic Monitoring (PAM).

(A) TGS shall conduct real-time passive acoustic monitoring by NMFS-approved passive acoustic monitor(s) using a towed hydrophone array from the support vessel throughout the open-water seismic surveys.

(B) Passive Acoustic Operator(s) and Monitor(s):

(I) Design and initial setup of PAM apparatus (including hardware and software) shall be done by experienced bioacoustician(s) with field experience in marine mammal passive acoustic monitoring and signal processing.

(II) Passive acoustic monitor(s) shall undergo basic training on PAM, and be able to operate independently once the PAM apparatus is set-up.

(III) Resumes for the bioacoustician(s) and passive acoustic monitor(s) candidates shall be provided to NMFS for review and acceptance of their qualifications.

(C) Specific sensor design and noise filters shall be used to maximize the system's ability to detect low frequency bowhead whales. To ensure the effectiveness of real-time PAM with a towed hydrophone array, the following requirements for PAM design and procedures are required:

(I) Limit towing speeds to 4–6 knots. Reduce speed appropriately, or change direction if necessary, so that if bowhead whales are detected so that bearing can be obtained. If greater speeds are necessary, slow down every 20–30 minutes to listen for animal calls for at least 5–10 minutes.

(II) Maintain a separation distance of at least several hundred meters (preferable more) from the seismic survey vessel.

(D) Best efforts shall be made without compromising data collection to localize vocalizing marine mammals.

(I) Use a signal conditioning system (i.e. filter and match signal gains) to allow software to effectively estimate bearings and/or localize.

(II) Use software designed exclusively for monitoring, localizing and plotting marine mammal calls.

(III) Design the sampling software to optimize overlap between monitoring the 180 and 160 dB isopleths.

(IV) Allow the support vessel to deviate from designated track-lines by 25–30 degrees (for brief periods) so that left/right ambiguity can be resolved if needed.

(8) Data Analysis and Presentation in Reports:

(a) Estimation of potential takes or exposures shall be improved for times with low visibility (such as during fog or darkness) through interpolation or possibly using a probability approach. Those data could be used to interpolate possible takes during periods of restricted visibility.

(b) To better assess impacts to marine mammals, data analysis shall be separated into periods when a seismic airgun array (or a single mitigation airgun) is operating and when it is not. Final report to NMFS should summarize and plot:

(i) Data for periods when a seismic array is active and when it is not; and

(ii) The respective predicted received sound conditions over fairly large areas (tens of km) around operations.

(c) To help evaluate the effectiveness of PSOs and more effectively estimate take, if appropriate data are available, TGS shall perform analysis of sightability curves (detection functions) for distance-based analyses.

(d) To better understand the potential effects of oil and gas activities on marine mammals and to facilitate integration among companies and other researchers, the following data should be obtained and provided electronically in the 90-day report:

(i) the location and time of each vessel-based sighting or acoustic detection;

(ii) position of the sighting or acoustic detection relative to ongoing operations (i.e., distance from sightings to seismic operation, etc.), if known;

(iii) the nature of activities at the time (e.g., seismic on/off);

(iv) any identifiable marine mammal behavioral response (sighting data should be collected in a manner that will not detract from the PSO of passive acoustic monitor's ability to detect marine mammals); and

(v) adjustments made to operating procedures.

(e) TGS shall provide useful summaries and interpretations of results of the various elements of the monitoring results, which shall include a clear timeline and spatial (map) representation/summary of operations and important observations. Any and all mitigation measures (e.g., vessel course deviations for animal avoidance, operational shut down) should be summarized. Additionally, an assessment of the efficacy of monitoring methods should be provided.

(f) TGS shall collaborate with other organizations operating in the Chukchi Sea and share visual and acoustic data to improve understanding of impacts from single and multiple operations and efficacy of mitigation measures.

(9) Reporting:

(a) Sound Source Verification Report: A report on the preliminary results of the sound source verification measurements, including the measured 190, 180, and 160 dB (rms) radii of the airgun sources and other acoustic survey equipment, shall be submitted within 14 days after collection of those measurements at the start of the field season. This report will specify the distances of the exclusion zones that were adopted for the survey.

(b) Throughout the survey program, PSOs shall prepare a report each day or at such other intervals, summarizing the recent results of the monitoring program. The reports shall summarize the species and numbers of marine mammals sighted. These reports shall be provided to NMFS.

(c) Seismic Vessel Monitoring Program: A draft report will be submitted to the Director, Office of Protected Resources, NMFS, within 90 days after the end of TGS' 2013 open-water seismic surveys in the Chukchi Sea. The report will describe in detail:

(i) summaries of monitoring effort (e.g., total hours, total distances, and marine mammal distribution through the study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals);

(ii) analyses of the effects of various factors influencing detectability of marine mammals (e.g., sea state, number of observers, and fog/glare);

(iii) species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover;

(iv) to better assess impacts to marine mammals, data analysis should be separated into periods when an airgun array (or a single airgun) is operating and when it is not. Final and comprehensive reports to NMFS should summarize and plot: (A) Data for periods when a seismic array is active and when it is not; and (B) The respective predicted received sound conditions over fairly large areas (tens of km) around operations.

(v) sighting rates of marine mammals during periods with and without airgun activities (and other variables that could affect detectability), such as: (A) Initial sighting distances versus airgun activity state; (B) closest point of approach versus airgun activity state; (C) observed behaviors and types of movements versus airgun activity state; (D) numbers of sightings/individuals seen versus airgun activity state; (E) distribution around the survey vessel versus airgun activity state; and (F) estimates of take by harassment.

(vi) reported results from all hypothesis tests should include estimates of the associated statistical power when practicable.

(vii) estimate and report uncertainty in all take estimates. Uncertainty could be expressed by the presentation of confidence limits, a minimum-maximum, posterior probability distribution, etc.; the exact approach would be selected based on the sampling method and data available.

(viii) The report should clearly compare authorized takes to the level of actual estimated takes.

(d) The draft report shall be subject to review and comment by NMFS. Any recommendations made by NMFS must be addressed in the final report prior to acceptance by NMFS. The draft report will be considered the final report for this activity under this Authorization if NMFS has not provided comments and recommendations within 90 days of receipt of the draft report.

(10)(a) In the unanticipated event that survey operations clearly cause the take of a marine mammal in a manner prohibited by this Authorization, such as an injury (Level A harassment), serious injury or mortality (e.g., ship-strike, gear interaction, and/or entanglement), TGS shall immediately cease survey operations and immediately report the incident to the Supervisor of the Incidental Take Program, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401 and/or by email to *Jolie.Harrison@noaa.gov* and *Shane.Guan@noaa.gov* and the Alaska Regional Stranding Coordinators (*Aleria.Jensen@noaa.gov* and *Barbara.Mahoney@noaa.gov*). The report must include the following information:

(i) time, date, and location (latitude/longitude) of the incident;

(ii) the name and type of vessel involved;

(iii) the vessel's speed during and leading up to the incident;

(iv) description of the incident;

(v) status of all sound source use in the 24 hours preceding the incident;

(vi) water depth;

(vii) environmental conditions (e.g., wind speed and direction, Beaufort sea state, cloud cover, and visibility);

(viii) description of marine mammal observations in the 24 hours preceding the incident;

(ix) species identification or description of the animal(s) involved;

(x) the fate of the animal(s); and

(xi) photographs or video footage of the animal (if equipment is available).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with TGS to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. TGS may not resume their activities until notified by NMFS via letter, email, or telephone.

(b) In the event that TGS discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (i.e., in less than a moderate state of decomposition as described in the next paragraph), TGS will immediately report the incident to the Supervisor of the Incidental Take Program, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov* and *Shane.Guan@noaa.gov* and the NMFS Alaska Stranding Hotline (1–877–925–

7773) and/or by email to the Alaska Regional Stranding Coordinators (*Aleria.Jensen@noaa.gov* and *Barabara.Mahoney@noaa.gov*). The report must include the same information identified in Condition 10(a) above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with TGS to determine whether modifications in the activities are appropriate.

(c) In the event that TGS discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the activities authorized in Condition 3 of this Authorization (e.g., previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), TGS shall report the incident to the Supervisor of the Incidental Take Program, Permits and Conservation Division, Office of Protected Resources, NMFS, at 301–427–8401, and/or by email to *Jolie.Harrison@noaa.gov* and *Shane.Guan@noaa.gov* and the NMFS Alaska Stranding Hotline (1–877–925–7773) and/or by email to the Alaska Regional Stranding Coordinators (*Aleria.Jensen@noaa.gov* and *Barbara.Mahoney@noaa.gov*), within 24 hours of the discovery. TGS shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. TGS can continue its operations under such a case.

(11) Activities related to the monitoring described in this Authorization do not require a separate scientific research permit issued under section 104 of the Marine Mammal Protection Act.

(12) The Plan of Cooperation outlining the steps that will be taken to cooperate and communicate with the native communities to ensure the availability of marine mammals for subsistence uses, must be implemented.

(13) This Authorization may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein or if the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals, or if there is an unmitigable adverse impact on the availability of such species or stocks for subsistence uses.

(14) A copy of this Authorization and the Incidental Take Statement must be in the possession of each seismic vessel operator taking marine mammals under the authority of this Incidental Harassment Authorization.

(15) TGS is required to comply with the Terms and Conditions of the Incidental Take Statement corresponding to NMFS' Biological Opinion.

Endangered Species Act (ESA)

The bowhead, fin, and humpback whales and ringed and bearded seals are the only marine mammal species currently listed as endangered or threatened under the ESA that could occur during TGS' proposed seismic surveys during the Arctic open-water season. NMFS' Permits and Conservation Division has initiated consultation with NMFS' Protected Resources Division under section 7 of the ESA on the issuance of an IHA to TGS under section 101(a)(5)(D) of the MMPA for this activity. Consultation will be concluded prior to a determination on the issuance of an IHA.

National Environmental Policy Act (NEPA)

NMFS is currently preparing an Environmental Assessment, pursuant to NEPA, to determine whether or not this proposed activity may have a significant effect on the human environment. This analysis will be completed prior to the issuance or denial of the IHA.

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to authorize the take of marine mammals incidental to TGS' 2013 open-water 2D seismic surveys in the Alaskan Chukchi Sea, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: June 6, 2013.

Donna S. Wieting,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2013–13988 Filed 6–11–13; 8:45 am]

BILLING CODE 3510–22–P

FEDERAL REGISTER

Vol. 78 Wednesday,

No. 113 June 12, 2013

Part V

The President

Presidential Determination No. 2013–09 of June 4, 2013—Suspension of Limitations Under the Jerusalem Embassy Act

Presidential Determination No. 2013–10 of June 5, 2013—Presidential Determination Pursuant to Section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012

Memorandum of June 7, 2013—Transforming Our Nation's Electric Grid Through Improved Siting, Permitting, and Review

Federal Register
Vol. 78, No. 113
Wednesday, June 12, 2013

Presidential Documents

Title 3—

The President

Presidential Determination No. 2013–09 of June 4, 2013

Suspension of Limitations Under the Jerusalem Embassy Act

Memorandum for the Secretary of State

Pursuant to the authority vested in me as President by the Constitution and the laws of the United States, including section 7(a) of the Jerusalem Embassy Act of 1995 (Public Law 104–45) (the ''Act''), I hereby determine that it is necessary, in order to protect the national security interests of the United States, to suspend for a period of 6 months the limitations set forth in sections 3(b) and 7(b) of the Act.

You are authorized and directed to transmit this determination to the Congress, accompanied by a report in accordance with section 7(a) of the Act, and to publish the determination in the *Federal Register*.

This suspension shall take effect after the transmission of this determination and report to the Congress.

THE WHITE HOUSE,
Washington, June 4, 2013.

[FR Doc. 2013–14130
Filed 6–11–13; 11:15 am]
Billing code 4710–10

Presidential Documents

Presidential Determination No. 2013–10 of June 5, 2013

Presidential Determination Pursuant to Section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012

Memorandum for the Secretary of State[,] the Secretary of the Treasury[, and] the Secretary of Energy

By the authority vested in me as President by the Constitution and the laws of the United States, after carefully considering the report submitted to the Congress by the Energy Information Administration on April 25, 2013, and other relevant factors, including global economic conditions, increased oil production by certain countries, and the level of spare capacity, I determine, pursuant to section 1245(d)(4)(B) and (C) of the National Defense Authorization Act for Fiscal Year 2012, Public Law 112–81, and consistent with my determinations of March 30, 2012, June 11, 2012, and December 7, 2012, that there is a sufficient supply of petroleum and petroleum products from countries other than Iran to permit a significant reduction in the volume of petroleum and petroleum products purchased from Iran by or through foreign financial institutions.

I will closely monitor this situation to ensure that the market can continue to accommodate a reduction in purchases of petroleum and petroleum products from Iran.

The Secretary of State is authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,

Washington, June 5, 2013.

[FR Doc. 2013–14131

Filed 6–11–13; 11:15 am]

Billing code 4710–10

Presidential Documents

Memorandum of June 7, 2013

Transforming Our Nation's Electric Grid Through Improved Siting, Permitting, and Review

Memorandum for the Heads of Executive Departments and Agencies

Our Nation's electric transmission grid is the backbone of our economy, a key factor in future economic growth, and a critical component of our energy security. Countries that harness the power of clean, renewable energy will be best positioned to thrive in the global economy while protecting the environment and increasing prosperity. In order to ensure the growth of America's clean energy economy and improve energy security, we must modernize and expand our electric transmission grid. Modernizing our grid will improve energy reliability and resiliency, allowing us to minimize power outages and manage cyber-security threats. By diversifying power sources and reducing congestion, a modernized grid will also create cost savings for consumers and spur economic growth.

Modernizing our Nation's electric transmission grid requires improvements in how transmission lines are sited, permitted, and reviewed. As part of our efforts to improve the performance of Federal siting, permitting, and review processes for infrastructure development, my Administration created a Rapid Response Team for Transmission (RRTT), a collaborative effort involving nine different executive departments and agencies (agencies), which is working to improve the efficiency and effectiveness of transmission siting, permitting, and review, increase interagency coordination and transparency, and increase the predictability of the siting, permitting, and review processes. In furtherance of Executive Order 13604 of March 22, 2012 (Improving Performance of Federal Permitting and Review of Infrastructure Projects), this memorandum builds upon the work of the RRTT to improve the Federal siting, permitting, and review processes for transmission projects. Because a single project may cross multiple governmental jurisdictions over hundreds of miles, robust collaboration among Federal, State, local, and tribal governments must be a critical component of this effort.

An important avenue to improve these processes is the designation of energy right-of-way corridors (energy corridors) on Federal lands. Section 368 of the Energy Policy Act of 2005 (the ''Act'') (42 U.S.C. 15926), requires the Secretaries of Agriculture, Commerce, Defense, Energy, and the Interior (Secretaries) to undertake a continued effort to identify and designate such energy corridors. Energy corridors include areas on Federal lands that are most suitable for siting transmission projects because the chosen areas minimize regulatory conflicts and impacts on environmental and cultural resources, and also address concerns of local communities. Designated energy corridors provide an opportunity to co-locate projects and share environmental and cultural resource impact data to reduce overall impacts on environmental and cultural resources and reduce the need for land use plan amendments in support of the authorization of transmission rights-of-way. The designation of energy corridors can help expedite the siting, permitting, and review processes for projects within such corridors, as well as improve the predictability and transparency of these processes. Pursuant to the Act, in 2009, the Secretaries of the Interior and Agriculture each designated energy corridors for the 11 contiguous Western States, as defined in section 368 of the Act. Energy corridors have not yet been designated

in States other than those identified as Western States. It is important that agencies build on their existing efforts in a coordinated manner.

By the authority vested in me as President by the Constitution and the laws of the United States of America, I hereby direct the following:

Section 1. *Principles for Establishing Energy Corridors.* (a) In carrying out the requirements of this memorandum regarding energy corridors, the Secretaries shall:

(i) collaborate with Member Agencies of the Steering Committee on Federal Infrastructure Permitting and Review Process Improvement (Steering Committee), established by Executive Order 13604, which shall provide prompt and adequate information to ensure that additional corridor designations and revisions are consistent with the statutory responsibilities and activities of the Member Agencies and enable timely actions by the Secretaries;

(ii) focus on facilitating renewable energy resources and improving grid resiliency and comply with the requirements in section 368 of the Act, by ensuring that energy corridors address the need for upgraded and new electric transmission and distribution facilities to improve reliability, relieve congestion, and enhance the capability of the national grid to deliver electricity;

(iii) use integrated project planning and consult with other Federal agencies, State, local, and tribal governments, non-governmental organizations, and the public early in the process of designating the energy corridors, so as to avoid resource conflicts to the extent practicable and make strategic decisions to balance policy priorities;

(iv) collaborate with State, local, and tribal governments to ensure, to the extent practicable, that energy corridors can connect effectively between Federal lands;

(v) minimize the proliferation of dispersed and duplicative rights-of-way crossing Federal lands while acting consistent with subsection (a)(ii) of this section;

(vi) design energy corridors to minimize impacts on environmental and cultural resources to the extent practicable, including impacts that may occur outside the boundaries of Federal lands, and minimize impacts on the Nation's aviation system and the mission of the Armed Forces; and

(vii) develop interagency mitigation plans, where appropriate, for environmental and cultural resources potentially impacted by projects sited in the energy corridors to provide project developers predictability on how to seek first to avoid, then attempt to minimize any negative effects from, and lastly to mitigate such impacts, where otherwise unavoidable. Mitigation plans shall:

(A) be developed at the landscape or watershed scale with interagency collaboration, be based on conservation and resource management plans and regional environmental and cultural resource analyses, and identify priority areas for compensatory mitigation where appropriate;

(B) be developed in consultation with other Federal agencies, State, local, and tribal governments, non-governmental organizations, and the public;

(C) include clear and measurable mitigation goals, apply adaptive management methods, and use performance measures to evaluate outcomes and ensure accountability and the long-term effectiveness of mitigation activities;

(D) include useful mechanisms, such as mitigation banks and in lieu fee programs, where appropriate for achieving statutory and regulatory goals; and

(E) be considered in the energy corridor designation process.

(b) The Secretary of Energy shall assess and synthesize current research related to the requirements set forth in subsection (a)(ii) of this section, such as transmission planning authority studies, congestion studies, and renewable energy assessments. Based on that analysis, the Secretary of Energy shall provide to the Steering Committee a Transmission Corridor Assessment Report (Report) that provides recommendations on how to best achieve the requirements set forth in subsection (a)(ii) of this section. Where research is available, the Report shall include an assessment of whether investment in co-locating with or upgrading existing transmission facilities, distributed generation, improved energy efficiency, or demand response may play a role in meeting these requirements. In preparing the Report, the Secretary of Energy shall consult with Federal, State, local, and tribal governments, affected industries, environmental and community representatives, transmission planning authorities, and other interested parties. The Report shall be provided in two parts. The first part, which shall provide recommendations with respect to the Western States, shall be provided by December 1, 2013, and the second part, which shall provide recommendations with respect to States other than the Western States, shall be provided by April 1, 2014.

Sec. 2. *Energy Corridors for the Western States.* (a) The Secretaries shall strongly encourage the use of designated energy corridors on Federal land in the Western States where the energy corridors are consistent with the requirements in this memorandum and other applicable requirements, unless it can be demonstrated that a project cannot be constructed within a designated corridor due to resource constraints on Federal lands. Additionally, the Secretaries, pursuant to section 368 of the Act, shall continue to evaluate designated energy corridors to determine the necessity for revisions, deletions, or additions to those energy corridors. Also, the Secretaries, coordinated by the Secretaries of the Interior and Agriculture, shall:

(i) by July 12, 2013, provide to the Steering Committee a plan for producing the Western corridor study and regional corridor assessments (as specified in subsection (a)(ii) and (a)(iii) of this section), which shall include descriptions of timelines and milestones, existing resources to be utilized, plans for collaborating with Member Agencies, and plans for consulting with other Federal agencies, State, local, and tribal governments, affected industries, environmental and community representatives, and other interested parties;

(ii) within 12 months of completion of the plan pursuant to subsection (a)(i) of this section, provide to the Steering Committee a Western corridor study, which shall assess the utility of the existing designated energy corridors;

(iii) provide to the Steering Committee regional corridor assessments, which shall examine the need for additions, deletions, and revisions to the existing energy corridors for the Western States by region. The regional corridor assessments shall evaluate energy corridors based on the requirements set forth in subsection (a) of section 1, the Report issued pursuant to subsection (b) of section 1, and the Western corridor study. The regional corridor assessments shall be completed promptly, depending on resource availability, with at least the first assessment completed within 12 months of completion of the plan pursuant to subsection (a)(i) of this section;

(iv) by November 12, 2014, provide to the Steering Committee and the Office of Management and Budget (OMB) an implementation plan for achieving the requirements set forth in subsections (a)(v) and (a)(vi) of this section based on the regional corridor assessments. The implementation plan shall include timelines and milestones that prioritize coordinated agency actions and a detailed budget;

(v) promptly after the completion of the regional corridor assessments and prioritized based on the availability of resources, undertake coordinated land use planning and environmental and cultural resource review processes to consider additions, deletions, or revisions to the current

Western energy corridors, consistent with the requirements set forth in subsection (a) of section 1, the Report required issued pursuant to subsection (b) of section 1, and the Western corridor study; and

(vi) as appropriate, after completing the required environmental and cultural resource analyses, promptly incorporate the designated Western corridor additions, deletions, or revisions and any mitigation plans developed pursuant to subsection (a)(vii) of section 1 into relevant agency land use and resource management plans or equivalent plans prioritized based on the availability of resources.

(b) The Member Agencies, where authorized, shall complete any required land use planning, internal policy, and interagency agreements to formalize the designation of energy corridors implemented pursuant to subsection (a)(vi) of this section. The Secretaries and Member Agencies shall also develop and implement a process for expediting applications for applicants whose projects are sited primarily within the designated energy corridors in the Western States, and who have committed to implement the necessary mitigation activities, including those required by the interagency mitigation plans required by subsection (a)(vii) of section 1.

Sec. 3. *Energy Corridors for the Non-Western States.* The Secretaries, in collaboration with the Member Agencies, shall continue to analyze where energy corridors on Federal land in States other than those identified as Western States may be necessary to address the recommendations in the Report issued pursuant to subsection (b) of section 1 and the requirements set forth in subsection (a) of section 1, and to expedite the siting, permitting, and review of electric transmission projects on Federal lands in those States. By September 1, 2014, the Secretaries shall provide the Steering Committee with updated recommendations regarding designating energy corridors in those States.

Sec. 4. *Improved Transmission Siting, Permitting, and Review Processes.* (a) Member Agencies shall develop an integrated, interagency pre-application process for significant onshore electric transmission projects requiring Federal approval. The process shall be designed to: promote predictability in the Federal siting, permitting, and review processes; encourage early engagement, coordination, and collaboration of Federal, State, local, and tribal governments, non-governmental organizations, and the public; increase the use of integrated project planning early in the siting, permitting, and review processes; facilitate early identification of issues that could diminish the likelihood that projects will ultimately be permitted; promote early planning for integrated and strategic mitigation plans; expedite siting, permitting, and review processes through a mutual understanding of the needs of all affected Federal agencies and State, local, and tribal governments; and improve environmental and cultural outcomes.

By September 30, 2013, Member Agencies shall provide to the Chief Performance Officer (CPO) and the Chair of the Council on Environmental Quality a plan, including timelines and milestones, for implementing this process.

(b) In implementing Executive Order 13604, Member Agencies shall:

(i) improve siting, permitting, and review processes for all electric transmission projects, both onshore and offshore, requiring Federal approval. Such improvements shall include: increasing efficiency and interagency coordination; increasing accountability; ensuring an efficient decision-making process within each agency; to the extent possible, unifying and harmonizing processes among agencies; improving consistency and transparency within each agency and among all agencies; improving environmental and cultural outcomes; providing mechanisms for early and frequent public and local community outreach; and enabling innovative mechanisms for mitigation and mitigation at the landscape or watershed scale; and

(ii) facilitate coordination, integration, and harmonization of the siting, permitting, and review processes of Federal, State, local, and tribal governments for transmission projects to reduce the overall regulatory burden while improving environmental and cultural outcomes.

Sec. 5. *General Provisions.* (a) The Secretaries and the Member Agencies shall coordinate the activities required by this memorandum with the Steering Committee and shall report to the Steering Committee their progress on meeting the milestones identified pursuant to this memorandum, consistent with the plans developed pursuant to sections 2 and 4 of this memorandum. The CPO shall report on the implementation of this memorandum in the report to the President submitted pursuant to section 2(e) of Executive Order 13604.

(b) In carrying out their responsibilities under this memorandum, Member Agencies shall consult relevant independent agencies, including the Federal Energy Regulatory Commission.

(c) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This memorandum shall be implemented consistent with Executive Order 13175 of November 6, 2000 (Consultation and Coordination with Indian Tribal Governments) and my memorandum of November 5, 2009 (Tribal Consultation).

(e) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of OMB relating to budgetary, administrative, or legislative proposals.

(f) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(g) The Director of OMB is hereby authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, June 7, 2013.

[FR Doc. 2013–14132
Filed 6–11–13; 11:15 am]
Billing code 3110–01

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