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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.

The Code of Federal Regulations is sold by the Superintendent of Documents.

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Parts 250 and 254

[Docket No. DOT–OST–2020–0251]

RIN 2105–AE81

Implementing Certain Provisions of the TICKETS Act and Revisions to Denied Boarding Compensation and Domestic Baggage Liability Limits

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Final rule; correcting amendments.

SUMMARY: The U.S. Department of Transportation (Department or DOT) published a final rule to, among other things, raise the liability limits for denied boarding compensation that U.S. and foreign air carriers may impose from the current figures of $675 and $1,350 to $775 and $1,550. That final rule became effective on April 13, 2021. This document corrects an editorial error in the rule text of that final rule. This document also makes several technical corrections to the regulation regarding oversales reporting.

DATES: This final rule is effective August 2, 2021. The correcting amendment to 14 CFR 250.5(b)(3) reflecting the dollar amount is applicable beginning April 13, 2021.

FOR FURTHER INFORMATION CONTACT: Clereece Kroha, Senior Trial Attorney, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–9342, 202–366–7152 (fax), *clereece.kroha@dot.gov* (email). You may also contact Blane Workie, Assistant General Counsel, Office of Aviation Consumer Protection, Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–9342, 202–366–7152 (fax), *blane.workie@dot.gov.*

SUPPLEMENTARY INFORMATION:

Correction to 14 CFR 250.5(b)(3): In the final rule published in the **Federal Register** of Wednesday, January 13, 2021 (86 FR 2534), there was an error in a dollar figure in § 250.5(b)(3). This dollar figure was $1,350 prior to April 13, 2021, and the January 13, 2021 final rule revised this figure according the formula set forth in 14 CFR 250.5(e) and applicable inflation indexes. The January 13, 2021 final rule inadvertently did not revise this dollar figure in the rule text. The figure should be ''$1,550'' instead of ''$1,350.''

Corrections to 14 CFR 250.10: 14 CFR 250.10 required certain air carriers to submit, on a quarterly basis, the information related to passengers denied confirmed space as specified in the Department's Bureau of Transportation Statistics (BTS) ''Form 251.'' This rule makes several technical corrections to the rule text of § 250.10 to reflect the recent revisions to BTS Form titled ''Report of Passengers Denied Confirmed Space.'' [1] Specifically, the form, previously named ''Form 251,'' is now named ''Form 250.'' Accordingly, this rule is changing all the references to ''Form 251'' in § 250.10 to ''Form 250.'' In addition, the form previously included reporting field ''Total Boardings'' on Line 7. On the revised form, the ''Total Boardings'' field is now on Line 6. This rule changes the reference of ''Total Boardings'' in ''Line 7'' in § 250.10 to ''Line 6.''

Section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553) provides that when an agency, for good cause, finds that notice and public procedure thereon are impractical, unnecessary, or contrary to the public interest, the agency may issue a final rule without providing notice and an opportunity for public comment (5 U.S.C. 553(b)(3)(B)). The Department has determined that there is good cause to issue these corrections to section 250.10 without notice and an opportunity for public comment because such notice and comment would be unnecessary. The technical changes made in this rule merely conform our regulations to reflect the changes to Form 250. The Department provided two notices and the opportunity for public comment on Form 250, consistent with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) and its implementing regulations, 5 CFR part 1320.[2] These technical changes provided in this notice do not change or amend any requirements from the rule's previous requirements and is not expected to impact carriers' current practice. For the same reason, the corrections to § 250.10 are effective August 2, 2021.

List of Subjects in 14 CFR Part 250

Air carriers, Consumer protection, Reporting and recordkeeping requirements.

Accordingly, 14 CFR part 250 is corrected by making the following amendments:

PART 250—OVERSALES

■ 1. The authority citation for part 250 continues to read as follows:

Authority: 49 U.S.C. 329 and chapters 41102, 41301, 41708, 41709, and 41712.

§ 250.5 [Amended]

■ 2. Section 250.5 is amended in paragraph (b)(3) by removing ''$1,350'' and adding ''$1,550'' in its place.

§ 250.10 [Amended]

■ 3. Section 250.10 is amended by removing ''Form 251'' wherever it appears and adding ''Form 250'' in its place, and in paragraph (a) by removing ''Line 7'' and adding ''Line 6'' in its place.

Dated: July 26, 2021.

Issued under authority delegated in 49 CFR 1.27(c).

John E. Putnam,

Acting General Counsel.

[FR Doc. 2021–16196 Filed 7–30–21; 8:45 am]

BILLING CODE 4910–9X–P

[1] See, *Notice of Submission of Proposed Information Collection to OMB; Agency Request for Revision of BTS Form 251 and Renewal of OMB Control Number 2138–0018: Part 250 of the Department's Economic Regulations—Oversales.* 85 FR 86990, Dec. 31, 2020.

[2] See, *Notice of Submission of Proposed Information Collection to OMB,* 85 FR 12668, March 3, 2020; *Notice of Submission of Proposed Information Collection to OMB; Agency Request for Revision of BTS Form 251 and Renewal of OMB Control Number 2138–0018: Par 250 of the Department's Economic Regulations—Oversales,* 85 FR 86990, December 31, 2020.

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

14 CFR Part 382

[Docket No. DOT–OST–2018–0068]

RIN No. 2105–AE63

Traveling by Air With Service Animals

AGENCY: Office of the Secretary (OST), U.S. Department of Transportation (DOT).

ACTION: Final rule; correcting amendment.

SUMMARY: The U.S. Department of Transportation (Department or DOT) published a final rule to amend the Department's Air Carrier Access Act (ACAA) regulation on the transport of service animals by air in the **Federal Register** on December 10, 2020. This document corrects the omission of an example in the applicability section of the rule text by adding it.

DATES: This correcting amendment is effective August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Maegan Johnson, Senior Trial Attorney, Office of Aviation Consumer Protection, U.S. Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–9342, 202–366–7152 (fax), *maegan.johnson@dot.gov* (email). You may also contact Blane Workie, Assistant General Counsel, Office of Aviation Consumer Protection, Department of Transportation, 1200 New Jersey Ave. SE, Washington, DC 20590, 202–366–9342, 202–366–7152 (fax), *blane.workie@dot.gov.*

SUPPLEMENTARY INFORMATION: When the Department amended the applicability section, 14 CFR 382.7, of its ACAA regulation on the transport of service animals, it inadvertently failed to instruct the **Federal Register** to retain the example scenario that followed the regulatory text in 14 CFR 382.7(c). This document corrects this error by reinstating the example after the amended regulatory text in 14 CFR 382.7(c).

List of Subjects in 49 CFR Part 382

Air carriers, Civil rights, Consumer protection, Individuals with disabilities, Reporting and recordkeeping requirements.

Accordingly, the Department of Transportation is amending 14 CFR part 382 by making the following correcting amendment:

PART 382—NONDISCRIMINATION ON THE BASIS OF DISABILITY IN AIR TRAVEL

■ 1. The authority citation for part 382 continues to read as follows:

Authority: 49 U.S.C. 41705.

■ 2. In § 382.7 amend paragraph (c) by adding example 1 to paragraph (c) to read as follows:

§ 382.7 To whom do the provisions of this part apply?

* * * * *

(c) * * *

Example 1 to paragraph (c): A passenger buys a ticket from a U.S. carrier for a journey from New York to Prague. The ticket carries the U.S. carrier's code and flight number throughout the entire journey. There is a change of carrier and aircraft in Frankfurt, and a foreign carrier operates the Frankfurt-Prague segment. The foreign carrier is not subject to the provisions of Part 382 for the Frankfurt-Prague segment. However, the U.S. carrier must ensure compliance with the applicable provisions of Part 382 on the Frankfurt-Prague segment with respect to passengers flying under its code, and the Department could take enforcement action against the U.S. carrier for acts or omissions by the foreign carrier.

* * * * *

Dated: July 26, 2021.

Issued under authority delegated in 49 CFR 1.27(n).

John E. Putnam,

Acting General Counsel.

[FR Doc. 2021–16194 Filed 7–30–21; 8:45 am]

BILLING CODE 4910–9X–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA–2021–0019]

RIN 0960–AI57

Extension of Expiration Date for Neurological Disorders Body System Listings

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: We are extending the expiration date of the body system, Neurological Disorders, in the Listing of Impairments (listings) in our regulations. We are making no other revisions to this body system in this final rule. This extension ensures that we will continue to have the criteria we need to evaluate neurological impairments at step three of the sequential evaluation processes for initial claims and continuing disability reviews.

DATES: This final rule is effective on August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Michael J. Goldstein, Director, Office of Medical Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–1020.

For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213, or TTY 1–800–325–0778, or visit our internet site, Social Security Online, at *http://www.socialsecurity.gov.*

SUPPLEMENTARY INFORMATION:

Background

We use the listings in appendix 1 to subpart P of part 404 of 20 CFR at the third step of the sequential evaluation process to evaluate claims filed by adults and children for benefits based on disability under the title II and title XVI programs.[1] 20 CFR 404.1520(d), 416.920(d), 416.924(d). The listings are in two parts: Part A has listings criteria for adults and Part B has listings criteria for children. If you are age 18 or over, we apply the listings criteria in Part A when we assess your impairment or combination of impairments. If you are under age 18, we first use the criteria in Part B of the listings when we assess your impairment(s). If the criteria in Part B do not apply, we may use the criteria in Part A when those criteria consider the effects of your impairment(s). 20 CFR 404.1525(b), 416.925(b).

Explanation of Changes

In this final rule, we are extending the date on which the listings for the following body system will no longer be effective as set out in the following chart:

[1] We also use the listings in the sequential evaluation processes we use to determine whether a beneficiary's disability continues. See 20 CFR 404.1594, 416.994, and 416.994a.

Body system listings	Current expiration date	Extended expiration date
Neurological Disorders (11.00 and 111.00)	September 29, 2021	September 29, 2025.

We continue to revise and update the listings on a regular basis, including those body systems not affected by this final rule.[2] We intend to update the listings affected by this final rule as necessary based on medical advances as quickly as possible, but may not be able to publish final rules revising these listings by the current expiration date. Therefore, we are extending the expiration date listed above.

Regulatory Procedures

Justification for Final Rule

We follow the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in promulgating regulations. Section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5). Generally, the APA requires that an agency provides prior notice and opportunity for public comment before issuing a final regulation. The APA provides exceptions to the notice-and-comment requirements when an agency finds there is good cause for dispensing with such procedures because they are impracticable, unnecessary, or contrary to the public interest.

We determined that good cause exists for dispensing with the notice and public comment procedures. 5 U.S.C. 553(b)(B). This final rule only extends the date on which the Neurological Disorders body system listings will no longer be effective. It makes no substantive changes to our rules. Our current regulations[3] provide that we may extend, revise, or promulgate the body system listings again. Therefore, we determined that opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, for the reasons cited above, we find good cause for dispensing with the 30-day delay in the effective date of this final rule. 5 U.S.C. 553(d)(3). We are not making any substantive changes to the Neurological Disorders body system listing. Without an extension of the expiration date for this listing, we will not have the criteria we need to assess medical impairments in the body system at step three of the sequential evaluation processes. We therefore find it is unnecessary to delay the effective date of this final rule.

Executive Order 12866, as Supplemented by Executive Order 13563

We consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the requirements for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563. Therefore, OMB did not review it. We also determined that this final rule meets the plain language requirement of Executive Order 12866.

Regulatory Flexibility Act

We certify that this final rule does not have a significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, a regulatory flexibility analysis is not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

These rules do not create any new or affect any existing collections and, therefore, do not require Office of Management and Budget approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

The Acting Commissioner of the Social Security Administration, Kilolo Kijakazi, having reviewed and approved this document, is delegating the authority to electronically sign this document to Faye I. Lipsky, who is the primary Federal Register Liaison for SSA, for purposes of publication in the **Federal Register**.

Faye I. Lipsky,

Federal Register Liaison, Office of Legislative and Congressional Affairs, Social Security Administration.

For the reasons set out in the preamble, we are amending subpart P of part 404 of chapter III of title 20 of the Code of Federal Regulations as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a) and (h)–(j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b) and (d)–(h), 416(i), 421(a) and (h)–(j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 by revising item 12 of the introductory text before Part A to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

* * * * *

12. Neurological Disorders (11.00 and 111.00): September 29, 2025.

* * * * *

[FR Doc. 2021–16417 Filed 7–30–21; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201 and 801

[Docket No. FDA–2015–N–2002]

RIN 0910–AI47

Regulations Regarding "Intended Uses"

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing a final rule to amend its medical product ''intended use'' regulations. This final rule amends FDA's regulations describing the types of evidence relevant to determining whether a product is intended for use as a drug or device under the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Public Health Service Act (PHS Act), and FDA's implementing regulations, including whether a medical product that is approved, cleared, granted marketing authorization, or exempted from

[2] We last revised the expiration date for the Neurological Disorders body system listings when we updated the body system on July 1, 2016 (81 FR 43038, 43052).

[3] See the first sentence of appendix 1 to subpart P of part 404 of 20 CFR.

premarket notification is intended for a new use. This action also withdraws and replaces the portions of a final rule issued on January 9, 2017, that never became effective.

DATES: This rule is effective September 1, 2021.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the ''Search'' box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Kelley Nduom, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5400, *kelley.nduom@fda.hhs.gov.*

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I. Executive Summary

A. Purpose of the Final Rule

FDA is taking this action to amend its existing regulations (§§ 201.128 and 801.4 (21 CFR 201.128 and 801.4)) describing the types of evidence relevant to determining a product's intended uses under the FD&C Act, the PHS Act, and FDA's implementing regulations. The amended regulations better reflect the Agency's current practices in evaluating whether a product is intended for use as a drug or device, including whether a medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification is intended for a new use. This action withdraws the portions of the final rule issued on January 9, 2017 (82 FR 2193), that never became effective, and it finalizes amendments to the intended use regulations for medical products that provide more clarity and direction to regulated industry and other stakeholders regarding the types of evidence relevant to determining a product's intended uses.

B. Summary of the Major Provisions of the Final Rule

FDA is finalizing amendments to its intended use regulations for medical products (§§ 201.128 and 801.4) to better reflect the Agency's current practices in evaluating whether a product is intended for use as a drug or device, including whether a medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification is intended for a new use.

Several comments on the proposed rule raised legal concerns. Some commenters argued that FDA should construe its statutory and regulatory authorities more narrowly, and some asserted that the proposed rule violates the First and Fifth Amendments. These and similar arguments have been raised in comments received during earlier stages of this rulemaking as well as in other rulemaking proceedings, petitions, and litigation involving intended use issues. A number of other comments raised questions about the rule's applicability to certain medical devices, such as devices that are exempt from premarket notification (510(k)) requirements. These comments also criticized the inclusion of language in the regulation clarifying that the design or composition of an article may be relevant to determining its intended use.

The final rule remains largely unchanged from the proposed rule. In response to comments received, we have modified the codified language of the intended use regulation for medical devices to clarify its applicability to devices that are approved, cleared, granted marketing authorization, or exempted from premarket notification. That is the only change from the codified language in the proposed rule.

C. Legal Authority

Among the provisions that provide authority for this final rule are sections 201, 403(r), 503(g), and 701(a) of the FD&C Act (21 U.S.C. 321, 343(r), 353(g), 371(a)); section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)); and sections 215, 301, 351(i) and (j), and 361 of the PHS Act (42 U.S.C. 216, 241, 262(i) and (j), and 264).

D. Costs and Benefits

The benefit of this final rule is the added clarity and certainty for firms and stakeholders regarding the evidence relevant to establishing whether a product is intended for use as a drug or device, including whether a medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification is intended for a new use. We do not have evidence that the final rule will impose costs on currently marketed products.

II. Meaning of Certain Terms in This Preamble

As used in this rulemaking, the following terms have the meanings noted below.

Term	Meaning
A medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification.	This term refers to a medical product that may be legally introduced into interstate commerce for at least one use under the FD&C Act or the PHS Act as a result of having satisfied applicable premarket statutory and regulatory requirements.

Term	Meaning
A medical use that is approved, cleared, granted marketing authorization, or exempted from premarket notification.	This term refers to an intended use included in the required labeling for an FDA-approved medical product, an intended use included in the indications for use statement for a device cleared or granted marketing authorization by FDA, or an intended use of a device that falls within an exemption from premarket notification.
Firms	This term refers to manufacturers, packers, and distributors of FDA-regulated products and all their representatives, including both individuals and corporate entities.
Healthcare providers	This term refers to individuals such as physicians, veterinarians, dentists, physician assistants, nurse practitioners, pharmacists, or registered nurses who are licensed or otherwise authorized by the State to prescribe, order, administer, or use medical products in a professional capacity.
Medical products	This term refers to drugs and devices, including human biological products.
Products unapproved for any medical use	This term refers to medical products that are not approved, cleared, granted marketing authorization, or exempted from premarket notification (as that phrase is described above) by FDA for any medical use, and which must be approved, cleared, granted marketing authorization, or exempted from premarket notification to be legally marketed for such use. This term also includes products that are marketed for non-medical uses, such as dietary supplements, conventional foods, and cosmetics.
Unapproved use of a medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification.	This term refers to an intended use that is not included in the required labeling of an FDA-approved medical product, an intended use that is not included in the indications for use statement for a device cleared or granted marketing authorization by FDA, or an intended use of a device that does not fall within an exemption from premarket notification.

III. Background

A. Introduction and History of This Rulemaking

The Agency issued a proposed rule in 2015 and a final rule in 2017 revising the language of its medical product intended use regulations, with the intent to conform them to the Agency's current practice in applying the regulations (see final rule, ''Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses''' (82 FR 2193, January 9, 2017)). These amendments did not reflect a change in FDA's approach regarding types of evidence of intended use for drugs and devices. However, after receiving a petition that requested the Agency reconsider these amendments, FDA delayed the effective date of the 2017 final rule and reopened the docket to invite public comment. A number of comments submitted during the reopening raised questions and, on March 16, 2018 (83 FR 11639), FDA delayed the effective date of the intended use amendments until further notice to allow further consideration of the substantive issues raised in the comments received. After considering the issues raised in the petition and comments submitted during the reopening, FDA issued a notice of proposed rulemaking in September 2020 (85 FR 59718, September 23, 2020, the ''NPRM'') to withdraw the portions of the final rule issued on January 9, 2017, that never became effective and to propose a new rule to provide more clarity regarding the types of evidence that are relevant in determining a product's intended uses.

B. Summary of Comments to the Proposed Rule

Approximately 15 comments on the proposed rule were submitted to the docket. These comments were submitted by various industry trade organizations, consumer advocacy groups, and individuals. Several comments raised legal concerns with the proposed rule, including arguments to the effect that the rule violates the First and Fifth Amendments. Other comments raised questions and concerns about the rule's applicability to certain medical devices, such as devices that are 510(k)-exempt. These comments also generally objected to the inclusion of language in the regulation clarifying that the design or composition of an article may be relevant to determining its intended use.

IV. Legal Authority

Among the statutory provisions that provide authority for this final rule are sections 201, 403(r), 503(g), and 701(a) of the FD&C Act, section 5(b)(3) of the Orphan Drug Act, and section 351(i) of the PHS Act. Section 201 of the FD&C Act defines ''drug'' (subsection (g)(1)), ''device'' (subsection (h)), ''food'' (subsection (f)), ''dietary supplement'' (subsection (ff)), ''cosmetic'' (subsection (i)), and ''tobacco product'' (subsection (rr)(1)); section 5(b)(3) of the Orphan Drug Act defines ''medical food''; and section 503(g)(1) of the FD&C Act provides that combination products are those ''that constitute a combination of a drug, device, or biological product.'' Section 351(i) of the PHS Act defines ''biological products'', and section 351(j) of the PHS Act provides that the requirements of the FD&C Act apply to biological products. Section 403(r) of the FD&C Act establishes the requirements under which certain labeling claims about uses of conventional foods and dietary supplements to reduce the risk of a disease or affect the structure or function of the human body are not evidence of intended use as a drug. Under section 701(a) of the FD&C Act, FDA has authority to issue regulations for the efficient enforcement of the FD&C Act. FDA regulates the manufacture, sale, and distribution of drugs, devices, combination products, tobacco products, foods (including dietary supplements), and cosmetics under the authority of the FD&C Act.

V. Comments on the Proposed Rule and FDA Responses

A. Introduction

We received approximately 15 comment submissions on the proposed rule by the close of the comment period, each containing one or more comments on one or more issues. We describe and respond to the comments in sections B through J of this section. We have numbered each comment to help distinguish between different comments. We have grouped similar comments together under the same number, and, in some cases, we have separated different issues discussed in the same comment and designated them as distinct comments for purposes of our responses. The number assigned to each comment or comment topic is purely for organizational purposes and does not signify the comment's value or importance or the order in which comments were received.

In addition to the comments specific to this rulemaking that we address in the following paragraphs, we received several general comments expressing support for or opposition to the rule. These comments express broad policy views and do not address specific points related to this rulemaking. Therefore, these general comments do not require a response. To the extent that comments expressing opposition to the rule requested that we refrain from finalizing the rule, we decline to do so. In general, comments outside the scope of this rulemaking have not been addressed here. Summaries of the remaining comments, as well as FDA's responses, are included in this document.

B. Comments and Responses Regarding Statutory and Regulatory Authority

(Comment 1) One comment asserted that under the relevant statutes, legislative history, and case law, evidence of intended use is limited to promotional claims that have been made in the marketplace. The comment argued that the NPRM was wrong in stating that evidence of intended use can be derived from ''any relevant source,'' including ''circumstances surrounding distribution.'' Other comments also encouraged the Agency to focus primarily or only on promotional claims.

(Response) We disagree. Nothing in the statute requires the narrow scope that the comment suggested. Although the first comment mentioned above loosely refers to the statutory and regulatory regime as support for its preferred interpretation, it does not cite any statutory language that dictates an exclusively claims-based approach to intended use. As four justices of the Supreme Court recognized in rejecting the argument that the statute limits evidence of intended use to promotional claims: ''The [FD&C Act] . . . does not use the word 'claimed'; it uses the word 'intended' '' (*FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 170 (2000) (dissenting opinion) (the majority declined to resolve the issue, *id.* at 131–32)). The fact that intended use can be established through promotional claims does not preclude the possibility that other evidence may be relevant as well.

Nor does the comment cite any legislative history that supports an exclusively claims-based approach to intended use. Indeed, the legislative history supports reliance on evidence of use by healthcare practitioners and consumers as relevant to intended use. The House Report on the Medical Device Amendments of 1976 states that ''[t]he Secretary may consider . . . use of a product in determining whether or not it is a device'' (see H.R. Rep. 853, 94th Cong., 2d Sess. 14 (1976), reprinted in An Analytical Legislative History of the Medical Device Amendments of 1976, Appendix III (Daniel F. O'Keefe, Jr. and Robert A. Spiegel, eds. 1976)). Similarly, the legislative history of the 1938 Act states expressly that ''the use to which the product is to be put will determine the category into which it will fall'' (see S. Rep. No. 361, 74th Cong., 1st Sess. 4 (1935), reprinted in 3 Legislative History 660, 663).

Nor does the language of the existing regulation support the commenter's position. ''[N]owhere does the regulation state that'' evidence of intended use is limited to statements or claims ''published to the marketplace'' (see *United States* v. *Vascular Solutions, Inc.,* 181 F. Supp. 3d 342, 347 (W.D. Tex. 2016)). Indeed, the existing regulations specifically state that evidence of intended use includes ''circumstances surrounding the distribution of the article'' and ''circumstances that the article . . . is offered or used for a purpose for which it is neither labeled or advertised.'' This language was included when the regulation was first codified in 1952 (see 17 FR 6818, 6820 (1952) (Ref. 1)).

Furthermore, the case law does not resolve the matter in favor of the position advanced by the commenter. Courts have repeatedly held that intended use is determined by looking to any relevant evidence, including statements and circumstances surrounding the manufacture and distribution of a medical product (see, *e.g., United States* v. *Article of 216 Cartoned Bottles, ''Sudden Change,''* 409 F.2d 734, 739 (2d Cir. 1969) (''It is well settled that the intended use of a product may be determined from its label, accompanying labeling, promotional material, advertising and any other relevant source.'') (citations omitted); *V.E. Irons, Inc.* v. *United States,* 244 F.2d 34, 44 (1st Cir. 1957) (observing that a court is ''free to look to all relevant sources in order to ascertain what is the 'intended use' of a drug'')). As explained by one court: ''Whether a product's intended use makes it a device depends, in part, on the manufacturer's objective intent in promoting and selling the product. All of the circumstances surrounding the promotion and sale of the product constitute the 'intent'. It is not enough for the manufacturer to merely say that he or she did not 'intend' to sell a particular product as a device. Rather, the actual circumstances surrounding the product's sale, such as the identi[t]y of actual customers and their use of the product and labeling claims, determine the 'intended' use of the product as a device under the Act'' (*United States* v. *789 Cases, More or Less, of Latex Surgeons' Gloves,* 799 F. Supp. 1275, 1285 (D. Puerto Rico 1992) (internal citations omitted)).

Courts have rejected the commenter's proposition that evidence of intended use is limited to a manufacturer's public claims concerning a device or drug (see *Nat'l Nutritional Foods Ass'n* v. *Matthews,* 557 F.2d 325, 334 (2d Cir. 1977) (''In determining whether an article is a 'drug' because of an intended therapeutic use, the FDA is not bound by the manufacturer's subjective claims of intent but can find actual therapeutic intent on the basis of objective evidence. Such intent also may be derived or inferred from labeling, promotional material, advertising, and any other relevant source.'') (internal citation and quotations omitted); *United States* v. *Travia,* 180 F. Supp. 2d 115, 119 (D.D.C. 2001) (''Labeling is not exclusive evidence of the sellers' intent. Rather, . . . 'it is well established that the intended use of a product, within the meaning of the [FD&C Act], is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source' . . . even consumer intent could be relevant, so long as it was pertinent to demonstrating the seller's intent . . . [I]f the government's allegations are true, the sellers did not need to label or advertise their product, as the environment provided the necessary information between buyer and seller. In this context, therefore, the

fact that there was no labeling may actually bolster the evidence of an intent to sell a mind-altering article without a prescription-that is, a misbranded drug.'') (citations omitted); *United States* v. *Vascular Solutions, Inc.,* 181 F. Supp. 3d at 347 (the position that evidence of objective intent is limited to statements ''published to the marketplace'' is ''absurd[]'')); see also *United States* v. *Storage Spaces Designated Nos. 8 and 49,* 777 F.2d 1363, 1366 n.5 (9th Cir. 1985) (concluding that products innocuously labeled as ''incense'' and ''not for drug use'' were in fact drugs where the ''overall circumstances'' demonstrated vendor's intent that products be used as cocaine substitutes); *United States* v. *An Article of Device Toftness Radiation Detector,* 731 F.2d 1253, 1257 (7th Cir. 1984) (intended use established in part by witness testimony that device had been used to treat patients, together with other evidence regarding a training program and financial arrangements offered by the defendant); *United States* v. *Undetermined Quantities of an Article of Drug Labeled as ''Exachol'',* 716 F. Supp. 787, 791 (S.D.N.Y. 1989) (explaining that ''FDA is not bound by the vendor's subjective claims of intent'' and that ''[a]n article intended to be used as a drug will be regulated as a drug . . . even if the product['']s labelling states that it is not a drug''); *United States* v. *22 Rectangular or Cylindrical Finished Devices,* 714 F. Supp. 1159, 1165 (D. Utah 1989) (''The objective intent referred to in the regulation may be shown not only by a product's labeling claims, advertising or written statements relating to the circumstances of a product's distribution, . . . but also by a product's actual use. See H.R. Rep. No. 853, 94th Cong., 14 (1976). . . . There also can be no dispute that the sterilizer, in its actual use, plays an integral role in the surgical treatment of patients.''); *Hanson* v. *United States,* 417 F. Supp. 30, 35 (D. Minn. 1976) (finding plaintiffs' beliefs that many people will die if they are deprived of the tablets and vials at issue relevant to establishing intended use), *aff'd,* 540 F.2d 947 (8th Cir. 1976); *United States* v. *Device Labeled ''Cameron Spitler Amblyo-Syntonizer'',* 261 F. Supp. 243, 245 (D. Neb. 1966) (''While claimant contends that the machines have not been represented as a cure for any particular eye malfunction, he admits the use of them in the treatment of certain eye maladies. Clearly, the seized machines are each a device within the meaning of § 321(h).'')).

Although one comment cited to several cases that relied only on promotional claims as evidence of intended use, only a very few, if any, cases have actually *excluded* non-claims evidence from consideration as evidence of intended use on the ground that the evidence was not promotional. The presence of claims may be particularly significant in determining intended use where a product, such as honey, does not have a therapeutic benefit or physiological effect (see, *e.g., United States* v. *An Article . . . ''U.S. Fancy Pure Honey'',* 218 F. Supp. 208, 211 (E.D. Mich. 1963) (claim that honey is a panacea for various diseases and ailments established the intended use as a drug), *aff'd,* 344 F.2d 288 (6th Cir. 1965). But the converse is *not* true—the absence of claims on a product that does have a physiological effect will not automatically render the product immune from FDA jurisdiction (see, *e.g., United States* v. *Carlson,* 810 F.3d 544 (8th Cir. 2016) (synthetic drugs, such as synthetic marijuana, labeled as incense, herbal incense, herbal potpourri, bath salts, etc., and that also bore the statement ''not for human consumption,'' found to be subject to FDA's jurisdiction as drugs)).

As FDA has explained, limiting evidence of intended use to only promotional claims would allow manufacturers to circumvent FDA regulation by masking their true intent, either by simply omitting explicit promotional claims or by making claims that are not true (for example, ''not for human use''). See 82 FR 14319 at 14321 through 14322 (March 20, 2017); 82 FR 2193 at 2196 (January 9, 2017); 80 FR 57756 at 57757 (September 25, 2015). As courts have recognized, ''[s]elf-serving labels cannot be allowed to mask the vendor's true intent as indicated by the overall circumstances.'' *United States* v. *Storage Spaces Designated Nos. 8 and 49,* 777 F.2d 1363, 1366 n.5 (9th Cir. 1985)). This is an issue that comes up frequently with respect to products in domestic commerce as well as imported goods and has resulted in FDA-issued warning letters, import refusals, civil injunction actions, and criminal prosecutions. FDA believes it is worth repeating the following previously cited examples, see 82 FR 14319 at 14321 through 14322 (March 20, 2017), of the types of situations in which evidence of intended use has been derived from sources other than explicit promotional claims:

- Persons distributing substances that are known to be used recreationally to achieve a mind-altering effect, such as dextromethorphan (the active ingredient in some cough suppressants) and nitrous oxide (which is a prescription drug) (see, *e.g., United States* v. *Johnson,* 471 F.3d 764, 765 (7th Cir. 2006); *United States* v. *Schraud,* 2007 U.S. Dist. LEXIS 89231, 3–6 (E.D. Mo. December 4, 2007); *United States* v. *Travia,* 180 F. Supp. 2d 115, 119 (D.D.C. 2001); *United States* v. *LA Rush,* 2:13–cr–00249, First Superseding Information (C.D. Cal. April 3, 2014)).
- Persons distributing synthetic drugs, such as synthetic marijuana, labeled as incense, potpourri, bath salts, and/or bearing the statement ''not for human consumption'' (see, *e.g., United States* v. *Carlson,* 810 F.3d 544 (8th Cir. 2016); *United States* v. *Carlson,* 12–cr–00305–DSD–LIB, Amended Superseding Indictment (D. Minn. Sept. 11, 2013) and Court's Instructions to the Jury, (D. Minn. October 8, 2013); *United States* v. *Bowen,* 14–cr00169–PAB, Indictment (D. Colo. May 5, 2014) and Rule 11(c)(1)(A) and (B) Plea Agreement and Statement of Facts Relevant to Sentencing (D. Colo. January 29, 2015).
- Persons distributing imitation drugs claimed to be incense or dietary supplements, such as imitation cocaine or imitation Ecstasy (see, *e.g., United States* v. *Storage Spaces Designated Nos. ''8'' & ''49'',* 777 F.2d 1363, 1366 (9th Cir. 1985); *United States* v. *Undetermined Quantities of . . . Street Drug Alternatives,* 145 F. Supp. 2d 692 (D. Md. 2001)).
- Persons distributing products containing the active ingredients in prescription drugs, such as VIAGRA, CIALIS, LEVITRA, or BOTOX, as less expensive alternatives to the approved products, with labeling that states that they are ''all natural'' or ''herbal'' supplements or ''for research only'' (see, *e.g., United States* v. *Dessart,* 823 F.3d 395 (7th Cir. 2016); *United States* v. *Zeyid,* 1:14–cr–0197, First Superseding Indictment (N.D. Ga. June 24, 2014) (see also Ref. 2); *United States* v. *Livdahl,* 459 F. Supp. 2d 1255, 1260 (S.D. Fla. 2005)).

Other instances where a person's claims about the intended use of a product are belied by the person's activities or non-promotional statements or by circumstantial evidence (see, *e.g., United States* v. *An Article of Device Toftness Radiation Detector,* 731 F.2d 1253, 1257 (7th Cir. 1984); *United States* v. *789 Cases of Latex Surgeons' Gloves,* 799 F. Supp. 1275, 1294–1295 (D.P.R. 1992)).

In these situations, the evidence relied on to establish intended use has included general knowledge of actual use by customers to achieve a mind-altering effect; the known effects of a product or substance; implied claims

from using names that sound similar to the names of controlled substances; the circumstances surrounding the sale (*e.g.,* a rock concert venue; receiving the product in bulk and repackaging into smaller plastic bags; the use of private email addresses; the absence of labeling); shipping orders, other correspondence, and memoranda relating to marketing and distribution; statements made in training sessions; and admissions.

Evidence other than promotional claims has also been used to establish that products offered for import into the United States without labeling or other claims that identify them as a drug or device are in fact intended for use as a drug or device and are therefore subject to refusal if it appears that they fail to meet certain requirements for importing medical products (see 21 U.S.C. 381(a)(3)). For example, the defendants in *United States* v. *Zeyid,* 1:14-cr-0197, First Superseding Indictment (N.D. Ga. June 24, 2014) (see Ref. 2), imported products containing active ingredients that were the same as those used in prescription drugs but that were labeled as ''tea,'' ''coffee,'' and ''beauty products.''

(Comment 2) One comment asserted that the position on intended use described by FDA in the NPRM was an ''alternative, novel interpretation [] with which FDA has flirted from time to time in the past.''

(Response) We disagree. This is not the first time FDA has responded to arguments that its interpretation of the scope of evidence relevant to ''intended use'' is too broad—those arguments have been raised in comments in earlier stages of this and other rulemaking proceedings, petitions, and litigation involving intended use issues. Contrary to the comment's assertion that the NPRM presented a novel interpretation of intended use, FDA has steadfastly maintained for decades that, in determining a product's intended use, the Agency may look to any relevant source of evidence, including a variety of direct and circumstantial evidence. FDA's position is reflected in the notices issued in this rulemaking over the past 5 years (see, *e.g.,* 85 FR 59718 at 59721 (September 23, 2020); 82 FR 14319 at 14320 (March 20, 2017); 82 FR 2193 at 2206 (January 9, 2017); 80 FR 57756 at 57757 (September 25, 2015)), and has been noted in court decisions (see, *e.g., Spectrum Pharma.* v. *Burwell,* 824 F.3d 1062, 1069 (D.C. Cir. 2016) (''To be sure, FDA recognizes that there may be situations in which it will look beyond just the manufacturer's statements [to determine intended use].''); *United States* v. *Travia,* 180 F. Supp. 2d 115, 119 (D.D.C. 2001) (''The government argues that the Court should look to the objective intent of the sellers in this case, which would permit the Court to view the totality of the circumstances—namely, the selling of balloons of laughing gas in the parking lot at a rock concert—surrounding the sale of the nitrous oxide here. See, *e.g.,* 21 CFR 201.128.'')). This position has also been explained in numerous litigation briefs and other FDA pronouncements, such as in the following excerpts from examples of such documents issued from 2000 to 2017:

- In determining a product's intended uses, ''[l]abeling is not [the] exclusive evidence.'' See *United States* v. *Travia,* 180 F. Supp. 2d 115, 119 (D.D.C. 2001). Instead, ''it is well established that the 'intended use' of a product, within the meaning of the Act, is determined from its label, accompanying labeling, promotional claims, advertising, and any other relevant source.'' *Action on Smoking and Health* v. *Harris,* 655 F.2d 236, 239 (D.C. Cir. 1980) (quotation marks omitted); see also *V.E. Irons, Inc.* v. *United States,* 244 F.2d 34, 44 (1st Cir. 1957) (''[W]e are free to look to all relevant sources in order [to] ascertain what is the 'intended use' of a drug.''). Courts have considered ''relevant sources'' to include, for example, product formulation and method of intake, actual use of the product by consumers and medical practitioners, and circumstances of sale in determining intended use. See, *e.g., United States* v. *Ten Cartons, More or Less, of an Article . . . Ener-B Vitamin B–12,* 72 F.3d 285, 287 (2d Cir. 1995); *United States* v. *Storage Spaces,* 777 F.2d 1363, 1367 (9th Cir. 1985); *United States* v. *An Article of Device . . . Toftness Radiation Detector,* 731 F.2d 1253, 1257–58 (7th Cir. 1984) (Litigation brief (2011), Ref. 3).
- Courts have recognized that intended use may be shown by non-speech evidence that has included, for example, product formulation and method of intake, actual use of the product by consumers and medical practitioners, and circumstances of sale (Litigation brief (2010), Ref. 4 at 8–9 n.5).
- Courts have repeatedly held that, although promotional claims are one source of evidence of intended use, FDA is authorized to rely on any other relevant source of evidence [including] . . . [the product's] method of intake, . . . [how any claims are] understood by a consumer. . ., [suggestive] product names, . . . [and] meta-tags (Litigation brief (2001), Ref. 5 at 20–26).
- [Evidence of intended use to be presented at trial includes:] (1) Defendant intended the nitrous oxide he was offering for sale on his website bongmart.com to be used as a drug, despite his marking the nitrous oxide 'For Food Use Only;' (2) Defendant knew that the nitrous oxide cartridges were commonly used as a drug for getting high; and (3) Defendant's customers actually used the nitrous oxide sold by Defendant as a drug (Litigation brief (2000), Ref. 6 at 6).
- It has been the Agency's longstanding position that in determining a product's intended use, the Agency may look to any relevant source of evidence. . . . To hold accountable firms that attempt to evade FDA drug jurisdiction by avoiding making express claims about their products or disclaiming a particular intended use, courts have relied on a variety of evidence to establish intended use, including general knowledge of actual use by customers to get high or have some other mind-altering effect; the known effects of a product or substance; implied claims from using names that sound similar to controlled substances; the circumstances surrounding the sale (*e.g.,* a rock concert venue; receiving the product in bulk and repackaging into smaller plastic bags; the use of private email addresses; the absence of labeling); shipping orders, other correspondence, and memoranda relating to marketing and distribution; statements made in training sessions; and admissions (Regulatory letter (2017), Ref. 7 at 9–10).
- The manufacturer's intent will necessarily be determined on a case-by-case basis, looking at the totality of the facts and circumstances. . . . The trier of fact will take into account the full body of evidence. If evidence of distribution or sponsorship activity forms part of the basis of FDA's claim, the trier of fact will consider the context of that activity . . . in assessing the manufacturer's objective intent (Regulatory letter (2002), Ref. 8 at 6).[1]

In addition, issues involving the scope of evidence relevant to establishing intended use frequently arise in FDA's day-to-day operations in protecting the public health, including Warning Letters and import determinations (see, *e.g.,* FDA Warning

[1] The comment erroneously asserts that FDA's reliance on evidence other than promotional claims to assert jurisdiction over cigarettes in a 1996 final rule was ''roundly rejected by the courts.'' In fact, the Supreme Court's majority opinion declined to address the issue, and the dissent endorsed FDA's analysis (see *FDA* v. *Brown & Williamson Tobacco Corp.,* 529 U.S. 120, 131–32 (2000); *id.* at 170 (dissenting opinion).

Letter to HelloCig Electronic Technology Co., Ltd (Ref. 9) (relying in part on undeclared active pharmaceutical ingredient as well as implied claims from imagery to determine product's intended use); FDA Warning Letter to Duy Drugs, Inc. (Ref. 10) (relying in part on undeclared sildenafil to establish intended use); Letter from Steven B. Barber, District Director, Cincinnati District, FDA to Marc C. Sanchez, Esq., Mood and Mind, LLC, (Ref. 7 at 9–10) (relying in part on known attributes and common uses of product to establish use; Letter from Daniel Solis, Director, Import Operations Branch, Los Angeles District to Carol A. Pratt, K&L Gates LLP (Ref. 11) (relying in part on information available on the internet reflecting general understanding by consumers of mind-altering properties and purported medical uses of product, as well as pattern of changes to the importer's website and blog to conceal the true intended use of the product by deleting references to the amount of a psychoactive component in the product); FDA Warning Letter to Lifetech Resources Labs Inc. (Ref. 12) (relying in part on ''presence of the prostaglandin analog, isopropyl cloprostenate, along with appearance claims'' to establish intended use); FDA Warning Letter to INZ Distributors (Ref. 13) (relying in part on presence of analogue of an erectile dysfunction drug to determine product's intended use)). One of the purposes of this rulemaking is to put to rest any dispute about FDA's interpretation of its statute and regulations, and its policy—as embodied in this rule as well as in the precedent cited above—regarding evidence that may be relevant to establishing intended use.

(Comment 3) With respect to the many situations where manufacturers and distributors attempt to evade FDA regulatory oversight by omitting promotional medical product claims, examples of which are provided above, one comment suggested that the Government could use other regulatory tools rather than apply FDA's authorities for premarket review of medical products. Specifically, the comment suggested that FDA employ ''a combination of post-market risk mitigation techniques'' which would require FDA to engage in the ''collection, review, and potential description in labeling'' of the risks associated with the ''unlabeled use'' before taking enforcement action against the product to protect the public health. The same comment suggested that, alternatively, FDA could consider evidence other than promotional claims, but only to establish that in fact a promotional claim had been made.

(Response) FDA declines this suggestion. The fundamental purpose of the FD&C Act is to help protect ''the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection'' (*United States* v. *Dotterweich,* 320 U.S. 277, 280 (1943)). ''[R]emedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health'' (*United States* v. *An Article of Drug . . . Bacto Unidisk,* 394 U.S. 784, 798 (1969)). Although FDA generally considers risk as part of its determination whether to take enforcement action, part of the impetus for Congress' development of the premarket review requirements was the determination that exclusive reliance on postmarket remedies, such as enforcement actions for false or misleading labeling, is inadequate because it does not prevent consumers from experiencing harm from unsafe and/or ineffective treatments.

FDA's position regarding evidence relevant to establishing intended use helps protect the public health. To describe more fully one of the examples cited above: In *United States* v. *Johnson,* 471 F.3d 764 (7th Cir. 2006), the defendant imported dextromethorphan hydrobromide (DXM), the active ingredient in some cough suppressants, and distributed it for recreational use. During the 4 months his company was in operation, five customers died. Because DXM is not a controlled substance, no charges were brought under the Controlled Substances Act, but the court found that FDA had jurisdiction under the FD&C Act (id. at 765). Defendant pleaded guilty to three counts of introducing a misbranded drug into interstate commerce and received a 77-month sentence (id.). In upholding that sentence, the Seventh Circuit noted that the defendant ''knew—not merely should have known—that there was a substantial risk that more of his customers would die, and yet he continued to sell DXM for recreational use and failed to warn existing customers, including the two teenagers who died after he learned of the first two deaths'' (id.).

Because FDA's position on intended use helps ensure that it can help curb the distribution of dangerous and fraudulent products, FDA declines to construe intended use more narrowly than the statute provides.

(Comment 4) One comment objected to FDA's statement in the proposed rule that relying exclusively on firms' claims to determine intended use would adversely affect public health by opening the door to the marketing of products that are unapproved for any medical use. The comment argued that there is no public health need for FDA to rely on evidence other than express claims to determine intended use because the FD&C Act and other statutes provide other authorities that allow FDA to take action against products that contain an active ingredient from an FDA-approved drug, controlled substance, or other pharmacological ingredient. Specifically, the comment recommended that FDA use its dietary supplement and food additive authorities to keep products containing pharmacological ingredients out of dietary supplements and conventional foods, rather than using an intended use analysis to classify and regulate the products as drugs. The specific authorities mentioned in the comment were the definitions of ''food'' and ''dietary supplement'' and the corresponding adulteration provisions of the FD&C Act; the premarket notification requirement for certain dietary ingredients not marketed in the United States before October 15, 1994; and the premarket approval requirement for food additives. Similarly, another comment argued that rather than continuing to take the approach to intended use outlined in the NPRM, the Government could apply other provisions of Federal law; and that where there are gaps in existing legal provisions, FDA could seek specific product-based legislative changes.

(Response) We decline the comments' suggestions. Although it is true that the authorities mentioned in the comment enable FDA to keep some products containing pharmacological ingredients out of the food supply and dietary supplement marketplace, the comment overstates the reach of FDA's other authorities and overlooks the fact that simply being outside the dietary supplement or food definition does not make a product unlawful and subject to enforcement action. To establish jurisdiction over a product as a drug and remove it from the marketplace, or require the manufacturer to obtain FDA approval for the product before marketing it, FDA must be able to establish that the product is a drug based on evidence of its intended use Thus, the regulatory tools the comment recommends are not a substitute for FDA's medical product authorities that include an intended use determination.

As the previous comment response explained, suggestions that FDA use other regulatory tools in place of

intended use would have a significant negative impact on public health. To protect consumers from dangerous products containing pharmacological ingredients like the cough suppressant in *United States* v. *Johnson* that caused several deaths, FDA intends to continue considering the full range of evidence relevant to determining intended use.

(Comment 5) One comment agreed with the NPRM that evidence of intended use could include conduct other than claims, but suggested that the rule clarify that the conduct must be promotional.

(Response) FDA declines this suggestion. FDA believes that the key issue in the intended use analysis is whether the evidence is ''relevant,'' which does not necessarily depend on whether there is evidence of ''promotional'' activity. The NPRM provided several examples to help inform the assessment of relevance. As the preamble explained, where a firm disseminates additional specific safety and warning information to healthcare providers to minimize the risk to patients receiving the drug for the unapproved use—an example of non-promotional speech—FDA would not consider such evidence to be relevant to intended use (see 85 FR 59718 at 59726). But the preamble provided other examples of evidence that would not necessarily be considered promotional that would still be relevant to intended use—such as designing a stent to be specifically sized for a use that is different from the purported use (see 85 FR 59718 at 59725). As another example, a factfinder might consider, as evidence of a new intended use, a spacer that the manufacturer claims can be used to elute one liquid, but is in fact designed with holes that are sized to elute a more viscous substance that contains a different active ingredient. Accordingly, FDA declines the suggestion to include ''promotional'' as a limiting principle for non-claims-based evidence that may be relevant to intended use.

This conclusion is consistent with recent case law. The case law describes the standard for determining intended use as ''all relevant evidence.'' This allows the fact finder to evaluate the facts of the specific case, which may involve a variety of situations and circumstances. For example, in *United States* v. *Carlson,* 810 F.3d 544 (8th Cir. 2016), defendants owned and/or worked at the Last Place on Earth, a head shop in Duluth, Minnesota, which sold synthetic drugs, such as synthetic marijuana. The products were labeled as incense, herbal incense, herbal potpourri, bath salts, etc., and also bore the label statement ''not for human consumption,'' but defendants knew that customers purchased them to consume as drugs (see id. at 549; see also Amended Superseding Indictment, 12–cr–00305–DSD–LIB ¶ 9 (D. Minn. September 11, 2013)). The trial court instructed the jury that the product's intended use ''is what a reasonable person would conclude the manufacturer, seller or dispenser of the product intended the product to be used for, based on all of the relevant information'' (see The Court's Instructions to the Jury, 12–cr–00305–DSD–LIB at 58 (D. Minn. October 8, 2013)). The court explained that the jury could consider ''any and all testimony and evidence,'' whether or not the manufacturer, seller, or dispenser made contrary claims or no claims (see id. at 58–59). All of the defendants were convicted of distributing misbranded drugs in violation of the FD&C Act (see *Carlson,* 810 F.3d at 550).

In *United States* v. *Dessart,* 823 F.3d 395 (7th Cir. 2016), the defendant used a website to sell products containing human growth hormone (''HGH''), steroids, and the active ingredients in the prescription drugs VIAGRA (sildenafil), CIALIS (tadalafil), and LEVITRA (vardenafil). Id. at 398. The website said that the products were ''for research only.'' Id. The defendant was indicted on 23 counts of violating the FD&C Act. Id. at 399. The court instructed the jury: ''[Y]ou should consider what a reasonable person would conclude the manufacturer or seller of the product intended the product to be used for, based on all of the relevant information. . . . You are not bound by any claims or statements made by the manufacturer or seller if there is other evidence concerning the use intended by the manufacturer or seller that conflicts with those claims or statements.'' Jury Instructions, Case No. 12–CR–85 at 4–5 (E.D. Wis. June 19, 2014). The jury convicted on all counts. *Dessart,* 823 F.3d at 400.

In *United States* v. *789 Cases of Latex Surgeons' Gloves,* 799 F. Supp. 1275, 1294–1295 (D.P.R. 1992), the Government sought condemnation of surgeon's gloves and their components, including cornstarch, stored in a rodent-infested facility. Although the product manufacturer argued that it did not intend for the gloves to be used in medical procedures, the court found that ''[t]he circumstances surrounding the manufacture, distribution, and actual use of Plastic Material's gloves present overwhelming evidence that claimant's gloves are intended for use as—and therefore are—devices within the meaning of the Act'': *e.g.,* the sole customer, the United States, purchased gloves only for medical use; and the cornstarch used to store the gloves was of a type used only with gloves intended for medical procedures.

In each of these cases, restricting relevant evidence to promotional claims and conduct could have led the factfinder to conclude that the products were outside of FDA's jurisdiction.

(Comment 6) One comment asserted that the phrase ''any relevant evidence'' as used in the case law should be understood, under the statutory interpretation principle *ejusdem generis,* to refer only to evidence of promotional claims.

(Response) FDA disagrees. First, most obviously, principles of statutory construction are not typically applied to language in court decisions. Second, throughout this preamble, we have cited numerous examples where courts and FDA have considered evidence other than promotional claims to be relevant to establishing intended use.

C. Comments and Responses Regarding the Design or Composition of an Article

(Comment 7) Several comments stated that FDA should reconsider the proposed regulatory text identifying evidence about the ''design or composition'' of an article as a type of evidence relevant to establishing intended use. Some comments also asserted that the characteristics and design of a medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification do not determine intended use and that intended use does not depend on the design of the product. Some comments requested that FDA remove this phrase from the codified language describing the types of evidence relevant to determining a product's intended uses.

(Response) We disagree with the comments and decline to remove ''design or composition'' from the codified language. As explained in the preamble, the revisions to the intended use regulations do not reflect a change in FDA's policies and practices. Rather, the amendments to the intended use regulations are intended to describe the types of evidence relevant to determining a product's intended use based on FDA's current practices. The design and composition of an article are examples of the types of evidence that may be relevant when determining the article's intended use. For example, FDA may consider the design or composition of a product, which includes product characteristics, when determining whether the product is ''intended to affect the structure or any

function of the body'' and therefore meets the device definition in section 201(h) of the FD&C Act (21 U.S.C. 321(h)). The addition of the phrase ''design or composition'' to the codified reflects FDA's longstanding and current policy that these are relevant to intended use.

As discussed in the preamble to the NPRM, an example of a situation where design features have been found relevant to intended use include the design of a stent to be specifically sized for a use that is different from the purported use (see 85 FR 59718 at 59725). Another example can be found in *United States* v. *Caputo,* 517 F.3d 935 (7th Cir. 2008), where the Seventh Circuit upheld a conviction for misbranding under the FD&C Act where design features were part of the evidence of intended use. There, the district court recited evidence of the differences in design between two versions of the device that necessitated separate premarket review applications: ''The larger sterilizer had different design and engineering characteristics: a six cubic foot chamber; a 5% peracetic acid mixture; different temperature, pressure, and gas flow rate; and a single, as opposed to multiple, use of the sterilant'' (*United States* v. *Caputo,* 456 F. Supp. 2d 970, 973 (N.D. Ill. 2006), *aff'd in relevant part,* 517 F.3d 935 (7th Cir. 2008)). As another example, a factfinder might consider, as evidence of a new intended use, a spacer that the manufacturer claims can be used to elute one liquid, but is in fact designed with holes that are sized to elute a more viscous substance that contains a different active ingredient.

Another example where composition has been found relevant to intended use is *United States* v. *Undetermined Quantities . . .''Pets Smellfree,''* 22 F.3d 235 (10th Cir. 1994). In that case, the Government had seized and sought to condemn ''Pets Smellfree'' as an adulterated and misbranded drug. The product was promoted as an animal food additive to reduce pet odor when ingested. In determining that the product was a drug, the Tenth Circuit relied heavily on expert testimony about the physiological effects of a pharmacologically active ingredient, chlortetracycline, in reducing the level of bacteria in the animals' digestive systems and oral cavities (see id. at 240). Other examples include *United States* v. *Zeyid,* 1:14-cr-0197, First Superseding Indictment (N.D. Ga. June 24, 2014) (see Ref. 2), where imported products labeled as ''tea,'' ''coffee,'' and ''beauty products'' contained active ingredients that were the same as those used in prescription drugs; FDA Warning Letter to HelloCig Electronic Technology Co., Ltd. (Ref. 9), where undeclared active pharmaceutical ingredient was considered relevant to intended use; and FDA Warning Letter to INZ Distributors (Ref. 13), where presence of analogue of an erectile dysfunction drug was considered relevant to intended use.

(Comment 8) Some comments suggested that consideration of ''design or composition of the article'' as a type of evidence of intended use may inhibit technological advancements and discourage manufacturers from developing products that, based on their design, may be used for multiple uses.

(Response) FDA disagrees with these comments. We do not believe that considering a product's design or composition to be relevant to the intended use of a product impedes technological advancements or discourages product development. As stated above, the relevance of a product's design and composition to intended use is a part of FDA's longstanding policy and has not hindered such improvements. For example, during premarket review of software, FDA may not always review a software device function that is included in the design but has been locked out, because it is not part of that specific premarket submission by the firm. If, however, the firm wants to unlock the software device function in the future, it must first obtain any necessary premarket clearance, marketing authorization or approval for the product with that function.

(Comment 9) One comment suggested that FDA should not seek enforcement after a product is approved, cleared, or granted marketing authorization solely based on that product's design or characteristics, and another comment suggested that FDA should not assert a new intended use based solely on such features.

(Response) FDA applies applicable premarket and postmarket statutory and regulatory requirements to determine whether a product is legally marketed. FDA examines all relevant evidence in assessing compliance with such requirements. As previously noted, FDA may consider a product's design or composition as one type of evidence relevant to the product's intended use.

D. Comments and Responses Regarding the First Amendment

(Comment 10) One comment stated that because the rule identifies speech as potentially relevant to establishing intended use, and such speech may be truthful, the rule is ''suspect'' under the First Amendment. The comment requested that FDA add specific statements to the codified language to address these concerns. Other comments similarly stated that the proposal does not adequately take into account the limitations on FDA's authority to regulate truthful and non-misleading speech.

(Response) We disagree that the rule is vulnerable under the First Amendment. First, as noted in the preamble to the NPRM, we do not believe this rulemaking implicates the First Amendment. The intended use regulations describe evidence that may be relevant to establishing intended use; they do not in themselves directly regulate speech (85 FR 59718 at 59723). Indeed, the changes to the codified language proposed and finalized in this rulemaking do not directly involve speech: Whether, and to what extent, a factfinder may rely on product design, product composition, and knowledge as evidence of intended use, is not itself a First Amendment question, because speech will not typically be involved in such evidence. See 82 FR 2193 at 2207.

Second, in the regulatory regime under the FD&C Act and the PHS Act, intended use helps determine the marketing status for products that are potentially subject to those Acts, which products Congress has directed FDA to regulate in the interest of the public health. Part of the regulatory regime for medical products involves, for example, the review of appropriate labeling in the context of premarket review and postmarket regulatory surveillance. The categorical exclusion of all truthful speech from regulatory review would undermine FDA's ability to promote and protect the public health through premarket review of medical products, including review of proposed labeling, and postmarket regulatory surveillance and actions.

For example, the Government prosecuted a clinic operator under the FD&C Act for injecting liquid silicone into the body to augment tissues such as the buttocks or breasts (Refs. 14 and 15). Silicone when used for industrial purposes would not fall within FDA's jurisdiction. However, in this case, evidence that helped establish the intended use of the products included testimony of victims about the claims made to them by the defendant that the product would enhance the size of their buttocks. Those claims may have been truthful in the sense that they revealed one effect of the product. However, the injection of liquid silicone into the body for tissue augmentation can result in serious adverse health consequences, including hardening of tissue at the injection site, embolization, and even

death. FDA has not approved any liquid silicone products for injection to augment tissues anywhere in the body. Therefore, it was in the interest of public health for FDA to take action against the person responsible for the administration of these products, and such action was well within FDA's jurisdiction and permissible under the First Amendment.

There are many industries whose operations involve some amount of communication with the public. The fact that those communications may be truthful does not shield those industries' operations from Government regulation. ''[I]t has never been deemed an abridgment of freedom of speech . . . to make a course of conduct illegal merely because the conduct was in part initiated, evidenced, or carried out by means of language, either spoken, written, or printed'' (*Rumsfeld* v. *Forum for Academic and Institutional Rights, Inc.,* 547 U.S. 47, 62 (2006) (citation omitted)). And, as the Court recently confirmed, '' 'the First Amendment does not prevent restrictions directed at commerce or conduct from imposing incidental burdens on speech' '' (*Barr* v. *Am. Ass'n of Political Consultants,* 140 S. Ct. 2335, 2347 (2020) (quoting *Sorrell* v. *IMS Health Inc.,* 564 U.S. 552, 567 (2011))).

Thus, as we explained in the NPRM, courts have long upheld the premarket review requirements of the FD&C Act and the PHS Act, and the role of intended use within that framework, as necessary to promote and protect the public health and as fully consistent with the First Amendment (see 85 FR 59718 at 59723). More specifically, courts have held that, under the holding of *Wisconsin* v. *Mitchell,* 508 U.S. 476, 489 (1993), the Government's reliance on speech as evidence of intended use under the FD&C Act does not infringe the right of free speech under the First Amendment (see, *e.g., Whitaker* v. *Thompson,* 353 F.3d 947, 953 (D.C. Cir. 2004); *Nicopure Labs, LLC* v. *FDA,* 944 F.3d 267, 283 (D.C. Cir. 2019); *United States* v. *Cole,* 84 F. Supp. 3d 1159, 1166 (D. Or. 2015); *United States* v. *Regenerative Sciences,* LLC, 878 F. Supp. 2d 248, 255–56 (D.D.C. 2012), *aff'd,* 741 F.3d 1314 (D.C. Cir. 2014); *United States* v. *Livdahl,* 459 F. Supp. 2d 1255, 1268 (S.D. Fla. 2005); *United States* v. *Lane Labs-USA, Inc.,* 324 F. Supp. 2d 547, 579–80 (D.N.J. 2004); see also *United States* v. *Article of Drug Designated B-Complex Cholinos Capsules,* 362 F.2d 923, 927 (3d Cir. 1966); *United States* v. *General Nutrition, Inc.,* 638 F. Supp. 556, 562 (W.D.N.Y. 1986)). Indeed, reliance on speech as evidence of intent is common in the law.[2]

Third, as also explained in the NPRM, even if this rulemaking or regulatory regime were appropriately subject to First Amendment review, FDA's consideration of speech as one type of evidence of intended use under its statutory and regulatory framework easily satisfies any applicable test. Under the *Central Hudson* framework, the threshold question is whether the speech is false or inherently or actually misleading or concerns unlawful activity—such speech may be prohibited (see *Central Hudson Gas & Elec. Corp.* v. *Pub. Serv. Comm'n,* 447 U.S. 557 (1980); *In re R.M.J.,* 455 U.S. 191, 203 (1982); *44 Liquormart, Inc.* v. *Rhode Island,* 517 U.S. 484, 497 n.7 (1996); *1–800–411–Pain Referral Serv., LLC* v. *Otto,* 744 F.3d 1045, 1056 (8th Cir. 2014)). When commercial speech relates to an illegal activity, there is no First Amendment interest to weigh against the governmental interest supporting the regulation of commercial activity (*Pittsburgh Press Co.* v. *Human Relations Comm'n,* 413 U.S. 376, 389 (1973)). Regulated parties cannot be allowed to escape reasonable Government regulations by ''bootstrap[ping] themselves into the heightened scrutiny of the First Amendment simply by infusing the prohibited conduct with some element of speech'' (*Ford Motor Co.* v. *Tex. DOT,* 264 F.3d 493, 506–507 (5th Cir. Tex. 2001)).

For example, in *United States* v. *Caputo,* 517 F.3d 935 (7th Cir. 2008), the court found that it did not need to resolve the question of whether promotional claims for an approved medical device were protected by the First Amendment because defendants' product was not approved: ''[t]here was no lawful activity for speech to promote'' (id. at 941). In *United States* v. *Cole,* 84 F. Supp. 3d 1159 (D. Or. 2015), defendants distributed unapproved products with claims that they treated diseases, including Alzheimer's and HIV infection. The court rejected defendants' First Amendment defense, explaining that, because ''[d]efendants' speech concerns an illegal activity—the introduction into interstate commerce of unapproved new drugs[,] . . . the First Amendment is not violated'' (id. at 1166–67). In *United States* v. *LeBeau,* 2016 U.S. Dist. LEXIS 13612 (E.D. Wisc. February 3, 2016), the court similarly rejected defendant's First Amendment defense to a charge of distributing an unapproved new drug and explained that, because defendant's speech occurred while promoting and distributing a product that was intended for treatment of diseases and had not been approved by the FDA, his commercial speech did not concern lawful activity and did not pass step (1) of *Central Hudson* (see id. at 29). The Seventh Circuit affirmed, explaining that ''[b]ecause LeBeau's statements promoted the unlawful sale of an unapproved drug, they were not entitled to protection'' (*United States* v. *LeBeau,* 654 Fed. App'x 826, 831 (7th Cir. 2016)).

Even where the threshold step of *Central Hudson* does not apply, FDA's reliance on speech as evidence of intended use in the context of premarket review directly advances, and is appropriately tailored to achieve, substantial public health interests and therefore satisfies the remaining steps of the *Central Hudson* analysis. The medical products FDA regulates have the potential to adversely impact public health and safety. The premarket review requirements of the FD&C Act and the PHS Act require companies to conduct scientific research to determine the safety and effectiveness of medical products before they are marketed and provide mechanisms to help ensure that protections are in place that will allow the public to obtain the benefits of these products while mitigating the risks. Accordingly, these premarket review provisions ''do not ban manufacturers from making accurate claims'' but instead ''require them to substantiate such claims.'' *Nicopure Labs, LLC* v. *FDA,* 944 F.3d 267, 285 (D.C. Cir. 2019).

(Comment 11) One comment asserted that the NPRM failed to provide a meaningful explanation of how its consideration of speech as evidence of intended use comports with the *Central Hudson* test, particularly whether there are any less speech-restrictive alternatives with respect to speech regarding unapproved uses of approved products. The comment cites *United States* v. *Caronia,* 703 F.3d 149 (2d Cir. 2012) and criticizes the Government for not providing a sufficient explanation of its consideration of less-restrictive alternatives in the context of that lawsuit. Another commenter similarly

[2] See Reference 16 (''This pattern in the law—using intent as the predicate for regulation and then using speech as evidence of intent—is quite common, and not peculiar to pharmaceutical regulation. As early as 1888, the Supreme Court affirmed a state court criminal conviction for someone who manufactured an 'oleaginous substance' otherwise perfectly legal, except that he intended for it to be used as food, and thereby his manufacture of it fell under the purview of a state regulator. Similarly, a hollow piece of glass with a bowl on the end is illegal drug paraphernalia only if intended for such illicit uses. An automobile is not subject to regulation by the Federal Aviation Administration, unless it is 'intended to be used for flight in the air.' '') (citations omitted).

asserted that the NPRM did not adequately justify under *Central Hudson* the Government's policy regarding off-label use/promotion.

(Response) Again, as noted above and in the NPRM, we do not believe this rulemaking implicates the First Amendment, particularly given that the changes to the codified language proposed and finalized in this rulemaking do not directly involve speech. As further explained in the NPRM, ''[b]ecause 'intended use' is only one element of an alleged violation of the FD&C Act, this rule does not itself implicate the First Amendment and does not attempt to resolve all First Amendment arguments that might be made by a firm in defending against an enforcement action under the FD&C Act.'' 85 FR 59798 at 59723 n.5. Nevertheless, in another proceeding, FDA has addressed in detail the issues raised by these comments (see Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products (January 2017) (Ref. 17)). Rather than repeat that analysis here, we summarize it briefly and incorporate the relevant portions of the document. The memorandum describes in detail the public health interests underlying and advanced by FDA's consideration of communications regarding unapproved uses of medical products that are approved, cleared, granted marketing authorization, or exempted from premarket notification as relevant to the premarket review requirements of the FD&C Act and PHS Act (see Ref. 17 at 3–16). As the memorandum explains, those requirements, among other things, motivate the development of scientific evidence that enables the reliable, population-level determination of the safety and efficacy of medical products for each intended use; require that the evidence be developed and independently reviewed before the products are marketed to the general public for each intended use; and require that the product bear labeling that identifies each medical use of the product that is approved, cleared, granted marketing authorization, or exempted from premarket notification and provides information for healthcare providers and patients on using the product safely and effectively for those uses that are approved, cleared, granted marketing authorization, or exempted from premarket notification. In the memorandum, FDA also examined alternative approaches suggested by the court in *United States* v. *Caronia,* as well as by commentators (see id. at 26–34). FDA explained that, although many of these proposed approaches addressed one or more of the interests served by the premarket review requirements, FDA found that none of them integrated the complex mix of numerous interests at play and thus none of the proposed approaches best advanced those multiple interests (see id.).

(Comment 12) One comment asserted that the right of a manufacturer to convey truthful and non-misleading information is protected under *Thompson* v. *Western States Medical Center,* 535 U.S. 357 (2002).

(Response) We disagree with the suggestion that *Western States* shields truthful and non-misleading speech from Government regulation. In that case, the Court applied the *Central Hudson* test to evaluate the regulation of the speech at issue, 535 U.S. at 368–77. In an analysis that broke no ''new ground'' (id. at 368), the Court explained that, in general, the Government should not restrict the communication of truthful and non-misleading information for the sole purpose of preventing members of the public from making bad decisions with the information (see id. at 374). However, that rationale is not applicable to this rulemaking because the premarket review requirements of the FD&C Act and PHS Act advance several different Government interests in protecting public health, as discussed above (see also Ref. 17).

(Comment 13) One comment asserted that the First Amendment protects not only the right to speak freely but also the right to hear and receive valuable information, and that this interest is particularly acute for the audience of physicians.

(Response) FDA has recognized that, under certain circumstances, both healthcare providers and patients may be interested in information about unapproved uses of products (see Ref. 17 at 17). In part because of this consideration, FDA has issued guidance documents describing circumstances in which the Agency does not intend to object to a firm's product communications or to view such communications as evidence of a new intended use (see 85 FR 59718 at 59723 & n.7). Nothing in this final rule reflects a change in FDA's policies and practices, as articulated in various guidance documents, regarding the types of firm communications that ordinarily would not, on their own, establish the firm's intent that a medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification be used for an unapproved use. As discussed elsewhere in this preamble, FDA declines the suggestion to expand the scope of this rulemaking to additional subjects.

(Comment 14) One comment referenced for support a 1999 district court decision in a case brought by Washington Legal Foundation. Another comment referenced the same litigation and asserted that FDA is subject to a permanent injunction curtailing the Agency's authority to bar manufacturers from sharing peer-reviewed medical texts and journal articles about off-label uses of their FDA-approved products.

(Response) We believe these comments have little bearing on the current rulemaking. First, as explained in the NPRM, the proposed revisions to the intended use regulations do not reflect any change in FDA's policies and practices, as articulated in various guidance documents, regarding the types of firm communications to which the Agency does not intend to object or to view as evidence of a new intended use. Among the guidance documents describing these existing policies are several that relate to the distribution of peer-reviewed medical texts and journal articles (see 85 FR 59718 at 59723 & n.7). Second, with respect to the district court decision referenced in the comments, the D.C. Circuit ''vacate[d] the district court's decisions and injunctions insofar as they declare the FDAMA and the CME Guidance unconstitutional'' (see *Washington Legal Found.* v. *Henney,* 202 F.3d 331, 337 (D.C. Cir. 2000); see also *Washington Legal Found.* v. *Henney,* 128 F. Supp. 2d 11, 15 (D.D.C. 2000) (holding that ''injunction has been wholly vacated by the Court of Appeals''); id. (holding that Court of Appeals ''vacated all of this Court's previous constitutional rulings on the matter''); 65 FR 14286 (2000) (describing FDA's understanding of the outcome of the *Washington Legal Found.* litigation); Letter from Margaret M. Dotzel, Assoc. Commissioner for Policy, FDA to Daniel J. Popeo & Richard A. Samp, Wash. Legal Found., Docket No. 01P–0250 (January 28, 2002) (same)).

(Comment 15) Some comments asserted that content-based restrictions on commercial speech are subject to strict scrutiny or heightened scrutiny. One comment argued that *Sorrell* v. *IMS Health Inc.,* 564 U.S. 552 (2011), *Reed* v. *Town of Gilbert,* 135 S. Ct. 2218 (2015), *Matal* v. *Tam,* 137 S. Ct. 1744 (2017), and *Barr* v. *Am. Ass'n of Political Consultants,* 140 S. Ct. 2335 (2020) support the proposition that all content-based speech restrictions, even

those involving commercial speech, are subject to strict scrutiny, effectively overruling the *Central Hudson* and *Wisconsin* v. *Mitchell* lines of cases. Relying primarily on *Sorrell* and mentioning *Barr,* another comment asserted that FDA understated the constitutional limits on its authority in the NPRM. Another comment suggested that heightened scrutiny is warranted under *Sorrell* in the fields of medicine and public health.

(Response) We disagree. As we discussed in the NPRM, the Supreme Court in *Sorrell* suggested that content- and speaker-based restrictions would be subject to ''heightened scrutiny,'' but nevertheless continued to apply the ''commercial speech inquiry'' as outlined in *Central Hudson* (85 FR 59718 at 59724 n.11). Several courts of appeals have subsequently concluded that *Sorrell* did not overrule or fundamentally alter the *Central Hudson* analysis (see *Retail Digital Network, LLC* v. *Prieto,* 861 F.3d 839, 846 (9th Cir. 2017) (en banc) (*Sorrell* ''did not mark a fundamental departure from *Central Hudson's* four factor test, and *Central Hudson* continues to apply'' to regulations of commercial speech, regardless of whether they are content based); *Missouri Broad. Ass'n* v. *Lacy,* 846 F.3d 295, 300 n.5 (8th Cir. 2017) (''The upshot [of *Sorrell*] is that when a court determines commercial speech restrictions are content- or speaker-based, it should then assess their constitutionality under *Central Hudson.*'') (quotation marks omitted; alteration in original); see also *Vugo, Inc.* v. *City of New York,* 931 F.3d 42, 50 (2d Cir. 2019) (''No Court of Appeals has concluded that *Sorrell* overturned *Central Hudson.* We agree with our sister circuits that have held that *Sorrell* leaves the *Central Hudson* regime in place, and accordingly we assess the constitutionality of the City's ban under the *Central Hudson* standard.''), *cert. denied,* 140 S. Ct. 2717 (2020)).

In *Reed* v. *Town of Gilbert,* the Court applied strict scrutiny to content-based restrictions on non-commercial speech in sign ordinances. Although some of the language in the majority opinion in that case is broad, most lower courts have subsequently rejected arguments that *Reed* applies to the regulation of commercial speech (see, e.g., *Vugo, Inc.* v. *City of New York,* 931 F.3d 42, 49–50 & n.6 (2d Cir. 2019) (holding that *Central Hudson* still applies to commercial speech after *Reed* and *Sorrell*), *cert. denied,* 140 S. Ct. 2717 (2020); *Nationwide Biweekly Admin., Inc.* v. *Owen,* 873 F.3d 716, 732 (9th Cir. 2017) (''*Reed* did not relate to commercial speech . . . and therefore did not have occasion to consider th[at] doctrine[.]'')). Indeed, as one comment noted, in *Matal* v. *Tam,* a decision regarding content-based commercial speech issued after *Reed,* only *one* Justice advocated overruling *Central Hudson* in favor of strict scrutiny (137 S. Ct. 1744, 1769 (2017) (Thomas, J., concurring in part and concurring in the judgment)). No other Justice joined that opinion. While no First Amendment analysis garnered five votes in *Matal,* one four-Justice opinion applied *Central Hudson* (id. at 1764); the other four-Justice opinion stated that heightened scrutiny should be applied to *viewpoint* discrimination, but explained that viewpoint discrimination is an ''egregious'' subcategory of content-based regulation, and further noted that regulations regarding product labeling or consumer protection may be evaluated differently from the trademark matter at issue in that case (id. at 1766, 1768).

There was similarly no majority First Amendment analysis in *Barr* v. *Am. Ass'n of Political Consultants,* 140 S. Ct. 2335 (2020). There, the plurality opinion explained that strict scrutiny should be applied to a law that singled out a specific subject matter for differential treatment—permitting robocalls for collecting money owed to the Government while prohibiting robocalls for all other purposes (see id. at 2346). Similarly, Justice Gorsuch's opinion emphasized that the statute under review favored certain voices while punishing others (see id. at 2364) (Gorsuch, concurring in the judgment in part and dissenting in part). In addition, the plurality opinion further circumscribed the scope of its holding: ''The issue before us concerns only robocalls to cell phones. . . . Our decision is not intended to expand existing First Amendment doctrine or to otherwise affect traditional or ordinary economic regulation of commercial activity'' (see id. at 2347; see also *Am. Hosp. Ass'n* v. *Azar,* 983 F.3d 528, 542 (D.C. Cir. 2020) (in upholding an HHS rule challenged in part on First Amendment grounds, the court distinguished *Barr* on the grounds that the restrictions in *Barr* involved political speech and the regulation at issue in *Am. Hosp. Ass'n* involved ordinary regulation of commercial activity)).

Accordingly, given that the Supreme Court has not overruled *Central Hudson* or *Wisconsin* v. *Mitchell* and given that the laws being reviewed in the cited cases were quite different from the premarket review provisions of the FD&C Act, we believe it would be wrong to conclude that the Supreme Court has implicitly but sweepingly reversed these long-standing precedents to invalidate the regulatory regime under the FD&C Act. And even if some form of heightened scrutiny were applicable to reliance on speech as evidence of intended use, FDA believes that the public health necessity of the premarket review provisions discussed in this preamble, including its references, justifies and necessitates this regime under any standard.

(Comment 16) One comment asserted that scientific speech has been recognized as core speech that merits the highest degree of constitutional protection, citing *Washington Legal Foundation* v. *Friedman,* 13 F. Supp. 2d 51, 62 (D.D.C. 1998).

(Response) FDA agrees that, in certain contexts, scientific speech merits the highest degree of constitutional protection. However, the comment failed to note that the cited opinion determined that scientific speech will be evaluated under the First Amendment as commercial speech when a commercial entity seeks to distribute it in order to increase its sales of the product (see id. at 64–65).

(Comment 17) One comment urged FDA to follow the Sixth Circuit's decision in *Int'l Outdoor, Inc.* v. *City of Troy,* 974 F.3d 690 (6th Cir. 2020), which the comment claimed held that all content-based speech restrictions are subject to strict scrutiny, even when the restrictions concern commercial speech.

(Response) FDA declines that suggestion for several reasons. First, *Int'l Outdoor*—like *Reed*—involved review of a sign ordinance, which does not raise the same complex regulatory and public health issues as premarket review under the FD&C Act and PHS Act. Second, a holding that strict scrutiny applies to all content-based commercial speech would run contrary to the weight of circuit court authority discussed above, including the Second Circuit's recent decision in *Vugo, Inc.* confirming that *Central Hudson* continues to govern review of commercial speech (see 931 F.3d at 50). Third, the Sixth Circuit in *Int'l Outdoor* did not actually hold that strict scrutiny applies to all content-based commercial speech; the Sixth Circuit distinguished *Vugo* on the ground that the Second Circuit case involved only commercial speech, where *Int'l Outdoor* involved both core and commercial speech (see 974 F.3d at 705).

(Comment 18) One comment asserted that FDA should not continue to rely on *Wisconsin* v. *Mitchell* and its progeny because the district court in *Amarin Pharma, Inc.* v. *FDA,* 119 F. Supp. 3d 196 (S.D.N.Y. 2015) construed *United*

States v. *Caronia,* 703 F.3d 149 (2d Cir. 2012) to foreclose that position. Another comment similarly argued that the NPRM understated the meaning and impact of *Caronia*.

(Response) We disagree. As we explained in the NPRM, the Second Circuit has explicitly confirmed—contrary to the cited conclusion in *Amarin*—that *Caronia* ''left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug's FDA-approved label.'' *United States ex rel. Polansky* v. *Pfizer, Inc.,* 822 F.3d 613 n.2 (2d Cir. 2016). And the Second Circuit has more generally confirmed the continued viability of the *Wisconsin* v. *Mitchell* theory after *Caronia,* finding a First Amendment challenge to reliance on speech to show an element of violation ''meritless'' because ''the speech is not 'itself the proscribed conduct.' '' *United States* v. *Pierce,* 785 F.3d 832, 841 (2d Cir. 2015) (quoting *Caronia,* 703 F.3d at 161). It is also noteworthy that the first comment did not cite any case other than *Amarin,* a district court decision on a motion for a preliminary injunction, in support of its position limiting the application of *Wisconsin* v. *Mitchell.* Indeed, decisions from other circuits issued after *Caronia* have upheld the application of *Wisconsin* v. *Mitchell* in the context of the premarket review requirements of the FD&C Act (see *Nicopure Labs, LLC* v. *FDA,* 944 F.3d 267, 283 (D.C. Cir. 2019); *United States* v. *Lebeau,* 654 Fed. App'x 826, 830–31 (7th Cir. 2016); *United States* v. *Facteau,* 2020 U.S. Dist. LEXIS 167169 (D. Mass. September 14, 2020); *United States* v. *Cole,* 84 F. Supp. 3d 1159, 1166 (D. Or. 2015)).

E. Comments and Responses Regarding the Fifth Amendment

(Comment 19) Some comments questioned the constitutionality of the intended use regulations and asserted that the Fifth Amendment requires that the boundaries between permissible and impermissible communications be clearly drawn, particularly with respect to matters involving speech. One comment criticized FDA's reliance on guidance documents to describe its enforcement policies in this regard.

(Response) While FDA agrees that laws must give a ''person of ordinary intelligence a reasonable opportunity to know what is prohibited,'' ''meticulous specificity'' is not required (see *Grayned* v. *City of Rockford,* 408 U.S. 104, 110 (1972)). The Supreme Court has recognized that laws may embody ''flexibility and reasonable breadth'' (see id.) and officials implementing them may ''exercise considerable discretion'' (see *Ward* v. *Rock Against Racism,* 491 U.S. 781, 794 (1989)), without the laws being declared unconstitutionally vague.

More specifically, the Supreme Court has held that ''perfect clarity and precise guidance have never been required even of regulations that restrict expressive activity'' (see *Ward,* 491 U.S. at 794 (citations omitted)). It is also well established that the use of an intent standard does not render a statute unconstitutionally vague (see *United States* v. *Williams,* 553 U.S. 285, 306 (2008); *Nat'l Ass'n of Manufacturers* v. *Taylor,* 582 F.3d 1, 26 (D.C. Cir. 2009) (''an intent standard is not per se vague, even in a statute regulating speech'')). Indeed, ''absent special circumstances not present here, there is no reason to conclude that the 'every day' task of assessing intent is inherently vague [even] when protected speech is involved'' (see *Taylor,* 582 F.3d at 27).

Moreover, courts have repeatedly rejected due process challenges to the FD&C Act as unconstitutionally vague or ambiguous. In *United States* v. *Hohensee,* 243 F.2d 367 (3d Cir. 1957), the Third Circuit rejected an unconstitutional vagueness challenge to provisions of the FD&C Act, which included the determination of intended use. In upholding the provisions, the court relied in part on the Supreme Court determination that the FD&C Act should ''be given a liberal interpretation to effectuate its high purpose of protecting unwary consumers in vital matters of health'' (see id. at 370; see also *United States* v. *Sullivan,* 332 U.S. 689, 695 (1948) (rejecting due process challenge to FD&C Act and finding no ambiguity in the misbranding language); *United States* v. *Caputo,* 517 F.3d 935, 941 (7th Cir, 2008) (rejecting argument that line between new and modified devices is too vague to be enforceable); *V.E. Irons* v. *United States,* 244 F.2d 34, 45 (First Cir. 1957) (rejecting as ''untenable'' the claim that the FD&C Act's misdemeanor misbranding provisions are unconstitutionally vague and upholding misbranding conviction for distribution of vitamin and mineral products shown to be intended for use as drugs.); *United States* v. *General Nutrition, Inc.,* 638 F. Supp. 556, 564 (W.D.N.Y. 1986) (''The Act on numerous occasions has been upheld against vagueness challenges . . . and this Court is unaware of any case holding any provision of the Act void for vagueness in any circumstance.'') (citations omitted)).

The first FDA regulation describing how ''intended use'' is determined was issued in 1952 (see 17 FR 6818, 6820 (1952) (Ref. 1)), and there have been only minor amendments since that time, including those being made through this rulemaking. Over nearly seven decades, medical product manufacturers have shown little difficulty in understanding how the regulations are applied. And, as noted in the NPRM, FDA has issued several guidance documents that describe circumstances in which the Agency does not intend to object to a firm's product communications or to view such communications as evidence of a new intended use (85 FR 59718 at 59723). FDA issues these guidance documents to better inform stakeholders regarding its policies, and feedback from stakeholders has generally been positive. The NPRM also goes further than previous rulemakings related to these regulations in providing illustrative examples of types of evidence that would and would not be relevant to establishing intended use. Accordingly, we do not believe that the intended use regulations are unconstitutionally vague.

F. Comments and Responses Regarding Definitions

(Comment 20) Some comments suggested clarifying and defining the terms ''intended use'' and ''indications for use'' as these terms are used for devices in § 801.4. One comment suggested defining these terms by adopting definitions used in other FDA regulations and guidance documents. The comment also suggested clarifying the definitions of ''intended use'' and ''indications for use'' as part of a substantial equivalence determination for a device and distinguishing these terms from the intended use regulations for drugs.

(Response) FDA disagrees with these comments. The intended use regulations, including § 801.4, describe the types of evidence relevant to determining a product's intended uses under the FD&C Act, the PHS Act, and FDA's implementing regulations. The term ''indications for use'' is not used in this rulemaking and as such, FDA does not believe there is a need to define the term here. Further, FDA's substantial equivalence determination during its review of a premarket notification is beyond the scope of this rulemaking.

(Comment 21) Several comments suggested revising § 801.4 to expressly include devices that are legally marketed without approval or clearance, such as devices exempt from premarket notification and granted marketing authorization. Some comments asserted that the terms ''approved or cleared medical products'' and ''approved or

cleared medical uses'' do not include such legally marketed devices and asked FDA to modify these terms to include 510(k)-exempt devices. One comment also suggested that FDA recognize how its review of drug and device labeling differ.

(Response) FDA agrees with adding language to § 801.4 to clarify that the regulation applies to devices that are exempt from premarket notification and devices that are granted marketing authorization through De Novo classification. We are adding the phrase ''granted marketing authorization, or exempt from premarket notification'' to the fourth sentence of § 801.4 to make this clarification.

FDA declines to compare FDA's review of drug and device labeling because such comparison is beyond the scope of this rulemaking.

(Comment 22) Some comments suggested defining the terms ''unapproved new use for an approved or cleared'' and ''unapproved use of an approved product'' in the codified. Another comment asserted that these terms were not consistently used throughout the preamble.

(Response) We have included related terms and phrases in the definitions section of the preamble above to help clarify our use of these and similar phrases. We do not believe that it is necessary to include these definitions in the codified language.

(Comment 23) Some comments requested FDA expressly include laboratorians in the definition of ''healthcare providers.''

(Response) The term ''healthcare provider'' includes a non-exhaustive list of individuals who are licensed or otherwise authorized by the State to prescribe, order, administer, or use medical products in a professional capacity. In some cases, this may include such licensed or otherwise State-authorized individuals with certain roles in a laboratory.

G. Comments and Responses Regarding ''Safe Harbors''

(Comment 24) A number of comments suggested modifications to FDA policies that the comments sometimes refer to as ''safe harbors'' for certain kinds of medical product communications. Some comments suggested the establishment of a ''safe harbor'' for scientific exchange, whereby scientific exchange would be excluded from determinations of intended use. Other comments suggested the creation of ''safe harbors'' for other types of communications, including discussions with healthcare providers about investigational uses, discussions held in the course of providing training or demonstrations to healthcare providers, market research about unapproved uses, and communications related to the collection of postmarket data. Another comment urged that FDA ''codify in binding regulations its policies regarding manufacturer communication of scientific and medical information,'' noting that guidance documents are not binding on enforcement authorities including the Department of Justice.

(Response) FDA welcomes and will continue to consider these comments related to ''safe harbors.'' However, the recommendations made in these comments go beyond the scope of this rulemaking, which is ''to conform §§ 201.128 and 801.4 to reflect how the Agency currently applies them to drugs and devices,'' 80 FR 57756 (2015). This rule, as proposed and as finalized, does not reflect a change in FDA's policies and practices regarding the types of firm communications that ordinarily would not, on their own, establish a new intended use. Expanding the scope of this rule to codify FDA's acknowledged ''safe harbors'' or to acknowledge additional ''safe harbors,'' as suggested in these comments, might warrant reproposing the rule to solicit additional input, unduly delaying the Agency's clarification of its regulations on intended use. Therefore, while FDA will continue to consider the issues raised by these comments, the Agency declines the present suggestions to modify its acknowledged ''safe harbors'' or codify them in the intended use regulation.

With regard to the suggestion that the Agency establish a ''safe harbor'' for scientific exchange, whereby scientific exchange would be excluded from determinations of intended use: the Agency notes that if all scientific exchange were excluded from determinations of intended use, companies might have an incentive to create and promote new intended uses for marketed products based on incomplete or otherwise flawed data. That outcome would not serve the public health. At the same time, FDA recognizes the importance of scientific exchange, including information regarding unapproved uses of products that healthcare providers may choose to take into account when making professional judgments regarding the use of medical products that are approved, cleared, granted marketing authorization, or exempted from premarket notification. Balancing these public health considerations, some of which are in tension with each other, is a complex and important task. FDA believes this rulemaking, the purpose of which is to finalize amendments to the intended use regulations, is not the appropriate forum to resolve separate questions relating to scientific exchange. As noted in the NPRM, FDA has issued several guidance documents that describe circumstances in which the Agency does not intend to object to a firm's medical product communications or to view such communications as evidence of a new intended use. See 85 FR 59718 at 59723 n.7. This final rule does not disturb any of FDA's acknowledged ''safe harbors,'' including those that encompass various types of scientific exchange. In addition, as discussed in the preamble to the proposed rule, a firm's knowledge of off-label use plus safe-harbored communication would not, without more, be determinative of a new intended use. See 85 FR 59718 at 59725.

H. Comments and Responses Regarding Examples

(Comment 25) One comment requests that FDA clarify, consistent with the Government's brief filed in *Par Pharmaceutical Inc.* v. *United States,* 1:11-cv-01820 (D.D.C.), that the example of ''repeated proactive detailing'' in the preamble to the proposed rule would not create a new intended use if the firm's communications with the healthcare professionals are consistent with the approved labeling.

(Response) FDA declines the suggestion because FDA does not believe the proposed clarification is warranted. As explained in the preamble, the revisions to the intended use regulations do not reflect a change in FDA's policies and practices, including as articulated in various guidance documents, regarding the types of firm communications that ordinarily would not, on their own, establish the firm's intent that a medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification be used for an unapproved use (see 85 FR 59718 at 59723). The NPRM references guidance documents including FDA Guidance for Industry, ''Medical Product Communications That Are Consistent With the FDA-Required Labeling—Questions and Answers,'' June 2018 (see id. Ref. 5). As explained in that guidance, FDA does not intend to rely exclusively on a firm's communication of information that is consistent with a medical product's FDA-required labeling to establish a new intended use. The example in the NPRM, however, describes a circumstance involving a patient population that does not fall within the product's approved population (see 85 FR 59718 at 59725) and, to the extent

the communication relates to a patient population outside the approved patient population reflected in the FDA-required labeling, the communication may not be considered consistent with the approved labeling. The *Par* brief cited in the comment confirms that a manufacturer's communication of information regarding an *approved use* to a physician whose patients do not fall within the product's approved population would not by itself establish a new intended use, but may be relevant together with other evidence in establishing the manufacturer's intent to distribute the product for an unapproved use (Ref. 3 at 17–18).

(Comment 26) Several comments requested modification to or clarification of the examples provided in section V.C. of the preamble to the proposed rule.

(Response) We decline to make the requested modifications to the examples. These examples were provided to illustrate evidence that, standing alone, would not be determinative of intended use, and they remain illustrative of that point. Although one comment suggested that the examples caused further confusion, most commenters indicated that the examples were helpful and encouraged FDA to offer additional examples. We continue to believe the examples provided in the preamble to the NPRM are helpful, and we are providing additional examples below. The list of examples in the proposed rule is not intended to be comprehensive or restrictive. Each scenario described in the preamble is fact-specific, and, under other circumstances or in other contexts, similar material may be evaluated differently.

(Comment 27) Several comments requested that FDA describe the intended use framework from the device industry perspective and provide additional device-specific examples.

(Response) The examples FDA provided in the preamble to the proposed rule were provided for illustrative purposes only and were not intended to be comprehensive or restrictive. In our responses to comments 7, 8, and 9 in this final rule preamble, we have provided additional examples of types of evidence [3] related to product design and composition that may be relevant when determining a medical device's intended use. Those examples describe evidence that *may be relevant,* but is not necessarily determinative, to establishing intended use.

To further clarify this regulation as it applies to devices, we are providing here additional device-specific examples of types of evidence that may be relevant, but are not necessarily determinative, in establishing intended use. As with the examples in the preamble to the proposed rule, the following examples are fact-specific and are provided for illustrative purposes only.

- Marketing a medical device with a name that implies a use to affect a particular organ or system of the body. Example: ''CardioCalm.''
- Designing a non-vascular stent with a coating clinically known to change calcification of blood vessels.
- Marketing a device that uses ultrasonic waves as a therapeutic massager, despite the fact that ultrasonic waves do not physically massage tissue but rather affect the underlying tissue through a sonic mechanism.

I. Comments on Codified Text and FDA Responses

(Comment 28) In the NPRM, FDA proposed to amend §§ 201.128 and 801.4 to provide that a firm would not be regarded as intending an unapproved new use for an approved drug or for a device approved, cleared, granted marketing authorization, or exempted from premarket notification based solely on that firm's knowledge that such drug or device was being prescribed or used by healthcare providers for such use. One commenter argued that FDA should delete ''solely'' from the regulations on intended use because this phrasing suggests that a firm's knowledge of unapproved use could be used in combination with other factors to determine the intended use of a product. Another commenter suggested that FDA should replace ''solely'' with a term that would clarify that such knowledge would be relevant only if such use is widespread and if a company's promotional activities are a primary reason for this widespread off-label use. This commenter also maintained that the final rule should be clear that only activities that are, at their core, promotional should be relevant for determining intended use.

(Response) FDA disagrees with these comments. The use of the word ''solely'' in §§ 201.128 and 801.4 is intended to convey that FDA does not intend to consider a firm's knowledge that a healthcare provider has used or prescribed the firm's medical product that has been approved, cleared, granted marketing authorization, or is exempt from 510(k) for an unapproved use, *by itself,* as sufficient to establish intended use. The removal of the word ''solely'' from the regulation and the suggestion that FDA consider only activities that are fundamentally promotional in determining intended use would be inconsistent with the Agency's longstanding position that determining a product's intended use is a fact-specific inquiry and that FDA may consider all relevant sources of evidence. These sources of evidence may include a firm's knowledge that a healthcare provider has used or prescribed the firm's medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification for an unapproved use, and may include activities that are not strictly promotional in nature. In short, direct promotion of the use is not necessary to establish intended use.

(Comment 29) One comment asked FDA to change ''article'' to ''device'' throughout § 801.4.

(Response) FDA disagrees with this suggestion. The use of the term ''article'' in §§ 201.128 and 801.4 is consistent with the use of that term in section 201 of the FD&C Act.

(Comment 30) A comment suggested deleting the phrase ''or used'' from the fourth sentence of § 801.4, asserting that a healthcare provider's use is not ''under the control of the firm.''

(Response) FDA disagrees with the comment's suggestion because, although the healthcare provider's use is not under the firm's control, what may be relevant to intended use is the firm's knowledge that the article is being used by the healthcare provider. As discussed above, both legislative history and the case law support reliance on actual use by healthcare providers as relevant to intended use. See, *e.g., United States* v. *An Article of Device Toftness Radiation Detector,* 731 F.2d 1253, 1257 (7th Cir. 1984); *United States* v. *22 Rectangular or Cylindrical Finished Devices,* 714 F. Supp. 1159, 1165 (D. Utah 1989); *United States* v. *Device Labeled* ''*Cameron Spitler Amblyo-Syntonizer,*'' 261 F. Supp. 243, 245 (D. Neb. 1966); H.R. Rep. No. 853, 94th Cong., 2d Sess. 14 (1976). However, a firm's knowledge that healthcare providers are prescribing or using its product that has been approved, cleared, granted marketing authorization, or is 510(k)-exempt for an

[3] As described in the preamble to the proposed rule, these types of evidence include express claims and representations; implied claims; product characteristics and design; and the circumstances of the product's sale or distribution (see 85 FR 59718 at 59725). In fulfilling its mission to protect the public health, FDA will evaluate the individual and unique circumstances of each case in determining a product's intended use. In some cases, a single piece of evidence may be dispositive of a product's intended use. In others, several elements combined may establish a product's intended use.

unapproved use would not, by itself, automatically trigger an obligation to provide labeling for that unapproved use.

(Comment 31) One comment suggested that FDA explain how § 801.4 applies to modifications of 510(k)-cleared devices.

(Response) FDA declines to adopt this suggestion because it is beyond the scope of this rulemaking.

(Comment 32) One comment stated that section 513(i)(1)(E) of the FD&C Act (21 U.S.C. 360c(i)(1)(E)) constrains how FDA ''responds to an intended use not reflected in device labeling when reviewing a 510(k)'' and that FDA ''cannot require that the company obtain clearance or approval of another potential unapproved use.'' The comment also suggested FDA disassociate intended use regulations for devices from drugs and add a reference to section 513(i)(1)(E) of the FD&C Act in the codified text of § 801.4.

(Response) FDA's application of section 513(i)(1)(E) of the FD&C Act is beyond the scope of this rulemaking.

J. Comments Recommending That FDA Expand the Scope of This Rulemaking

(Comment 33) A number of comments urged FDA to expand this rulemaking beyond the scope of the proposed rule. For example, one comment urged FDA to ''complete its long-promised 'comprehensive review' of regulations to assess alignment with constitutional and statutory requirements.'' Another comment proposed that FDA adopt a regulatory approach to manufacturer speech consistent with the ''Principles on Responsible Sharing of Truthful and NonMisleading Information About Medicines with Health Care Professionals and Payers'' developed by Pharmaceutical Research and Manufacturers of America and the Biotechnology Innovation Organization.

(Response) Although FDA welcomes the submission of ideas regarding a broader list of suggested policy changes, we decline to adopt the suggestions in these comments because they are beyond the scope of this rulemaking. Expanding the scope of this rule as suggested in these comments would potentially delay FDA's clarification of its regulations on intended use. FDA has been engaged in a continuing review of regulations and policies regarding communications with healthcare providers and payors (and other similar entities with knowledge and expertise in healthcare economic analysis) regarding medical products, and has taken other initiatives as part of that effort.

(Comment 34) One comment contended that the regulatory requirements for premarket approval and authorization are too burdensome so that it is unreasonable to require that manufacturers conduct studies and submit applications for every intended use.

(Response) This comment also raises issues that are different from and beyond the scope of this rulemaking. To the extent this comment is suggesting that the best way to address complex questions concerning premarket authorization is through limiting the scope of intended use, we disagree that this is an appropriate tool.

(Comment 35) One comment requested that FDA acknowledge that healthcare providers may prescribe and use approved/cleared medical products for unapproved uses when they judge that the unapproved use is medically appropriate for their patients and that manufacturers are not required to confirm the nature of a healthcare provider's planned use for an approved medical product before distributing such product to the healthcare provider.

(Response) Healthcare providers prescribe or use medical products that are approved, cleared, granted marketing authorization, or exempted from premarket notification for unapproved uses based on their medical judgment regarding any potential benefits and risks of the unapproved use for their individual patients.[4] In these limited circumstances, FDA's longstanding position is that the Agency does not consider a firm's knowledge that a healthcare provider has used or prescribed its medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification for an unapproved use, by itself, as sufficient to establish the intended use element of a prohibited act based on failing to meet applicable premarket requirements for that use or failing to provide adequate directions for use.[5]

VI. Effective Date

This final rule will become effective 30 days after the date of its publication in the **Federal Register**.

VII. Economic Analysis of Impacts

A. Introduction and Summary

1. Introduction

We have examined the impacts of the final 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 us 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). This final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. We cannot predict how many companies may revise labeling, advertising, or other materials, or otherwise modify their behavior, following issuance of this rule. However, this rule would merely clarify, but not change, the types of evidence relevant to determining manufacturers' intended use of products. Because the rule would not extend FDA's authority to additional products or impose any additional requirements on currently regulated products, we expect the rule will impose negligible costs, if any. As a result, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal

[4] FDA generally does not seek to interfere with the exercise of the professional judgment of healthcare providers in prescribing or using, for unapproved uses for individual patients, most legally marketed medical products. This longstanding position has been codified with respect to devices (see 21 U.S.C. 396). Although FDA generally does not seek to interfere with the exercise of the professional judgment of veterinarians, certain unapproved uses of drugs in animals are not permitted (see section 512(a)(4) and (5)) of the FD&C Act (21 U.S.C. 360b(a)(4) and (5) and 21 CFR part 530) and result in the drug being deemed ''unsafe'' and therefore adulterated under sections 512 and 501(a)(5) (21 U.S.C. 351(a)(5)) of the FD&C Act.

[5] See 21 U.S.C. 331(d), 351(f), 352(f)(1), 355(a). The position described in the text does not apply to products that are not already legally marketed as medical products for at least one use. Similarly, nothing in this regulation or preamble is intended to impact the application of 21 U.S.C. 333(e), which, subject to limited exceptions, penalizes anyone who ''knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of disease or other recognized medical conditions, where such use has been authorized by the Secretary of Health and Human Services under section 505 and pursuant to the order of a physician.'' Further, Congress or the Agency could promulgate other provisions regarding specific products or classes of medical products that recognize knowledge as sufficient evidence of a particular element of a prohibited act.

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 $158 million, using the most current (2020) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

2. Summary of Costs and Benefits

The final rule clarifies but does not change FDA's interpretation and application of existing intended use regulations for medical products.

The benefits of this rule are additional clarity and certainty for manufacturers and stakeholders regarding evidence that is relevant in evaluating whether an article is intended for use as a drug or device.

This final rule is not expected to impose any significant additional costs on firms. Although this rule may impact firms' future marketing, product development, and communication strategies, firms are not required to make any changes to labeling, marketing materials, or operating procedures. Additionally, this rule does not extend FDA's jurisdiction to any new products.

TABLE 1—SUMMARY OF BENEFITS, COSTS, AND DISTRIBUTIONAL EFFECTS OF FINAL RULE

Category	Primary estimate	Low estimate	High estimate	Units			Notes
				Year dollars	Discount rate (%)	Period covered	
Benefits:							
Annualized Monetized $millions/year					7		
					3		
Annualized Quantified					7		
					3		
Qualitative	Clarification of intended use interpretation and application						
Costs:							
Annualized Monetized $millions/year					7		
					3		
Annualized Quantified					7		
					3		
Qualitative	Negligible costs, if any						
Transfers:							
Federal Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			
Other Annualized Monetized $millions/year					7		
					3		
From/To	From:			To:			

Effects:
State, Local or Tribal Government: None.
Small Business: None.
Wages: None.
Growth: None.

3. Comments on the Preliminary Economic Analysis of Impacts and Our Response

We did not receive any comments on the Preliminary Economic Analysis of Impacts.

4. Summary of Changes

We have made no significant changes from the Preliminary Economic Analysis of Impacts.

B. Final Economic Analysis of Impacts

1. Background

This rule clarifies FDA's longstanding position that the intended use of a drug or device product can be based on any relevant source of evidence by describing types of evidence relevant to the intended use of a product and types of evidence that, standing alone, are not determinative of intended use.

One important clarification involves a manufacturer's knowledge of unapproved uses of its approved product. Current versions of §§ 201.128 and 801.4 specify that a manufacturer of a drug (§ 201.128) or device (§ 801.4) must include adequate labeling if it knows its product is used for an unapproved purpose. The September 2015 proposed rule (80 FR 57756 at 57764) removed the sentence regarding the requirement to provide adequate labeling if a firm knows its product is being used for an unapproved use. The amended January 2017 final rule (82 FR 2193 at 2217) was intended to clarify FDA's position by requiring manufacturers to include adequate labeling ''if the totality of the evidence establishes that a manufacturer objectively intends that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than ones for which it is approved (if any).''

In the **Federal Register** of February 7, 2017 (82 FR 9501), FDA delayed the effective date of the January 2017 final rule until March 2017. In February 2017, various industry organizations filed a petition raising concerns with the January 2017 final rule, requesting reconsideration and a stay. The petition requested that FDA reconsider the amendments to the ''intended use'' regulations and issue a new final rule that, with respect to the intended use regulations at §§ 201.128 and 801.4, reverted to the language of the September 2015 proposed rule. The

petition also requested that FDA indefinitely stay the rule because petitioners argued that the final rule was issued in violation of the fair notice requirement under the Administrative Procedure Act and that the ''totality of the evidence'' language in the 2017 final rule was a new and unsupported legal standard.

In the **Federal Register** of March 20, 2017 (82 FR 14319), FDA further delayed the effective date of the final rule until March 2018 and opened the docket for additional public comment. Following some comments supporting the delay and proposing specific changes to the language in §§ 201.128 and 801.4, on March 16, 2018 (83 FR 11639), FDA delayed the amendments to §§ 201.128 and 801.4 until further notice. This final rule adopts the general approach set forth in the September 2015 proposed rule by deleting the final sentence; the final rule also clarifies FDA's interpretation and application of evidence relevant to determining intended use.

2. Benefits of the Final Rule

The final rule clarifies FDA's existing interpretation of the determination of the intended use of drugs and devices. This clarification should reduce manufacturer and stakeholder uncertainty regarding the scenarios in which specific types of evidence may or may not show a product is intended for a drug or device use. The removal of the final sentence in §§ 201.128 and 801.4 and the inclusion of new clarifying clauses (''provided, however, that a firm would not be regarded as intending an unapproved new use for [a medical product that is approved, cleared, granted marketing authorization, or exempted from premarket notification] based solely on that firm's knowledge that such [product] was being prescribed or used by health care providers for such use'') resolve questions about whether manufacturers need to think about developing an action plan or strategy related to a potential new intended use of their medical products that are approved, cleared, granted marketing authorization, or exempted from premarket notification simply because a manufacturer has knowledge of unapproved uses of these products by third parties. We believe this clarification is the benefit of the final rule.

3. Costs of the Final Rule

The final rule is not expected to impose significant additional costs on manufacturers and distributors of FDA-regulated products. The final rule does not extend FDA's regulatory authority to any new or additional products, nor does the rule change the current approach to evaluating intended use or impose any additional requirements on manufacturers or distributors. We do not have any reason to believe firms will change their marketing or operating procedures as a result of this rule. We do not have evidence that this final rule would impose costs on currently marketed products.

C. Final Small Entity Analysis

In table 2, we describe the Small Business Administration's size thresholds for industries affected by the final rule. Based on U.S. Census data, at least 22.9 percent of businesses in NAICS code 21323 (Tobacco Manufacturing) are considered small; at least 17.5 percent of businesses in NAICS code 32541 (Pharmaceutical and Medicine Manufacturing) are considered small; and at least 32.6 percent of businesses in NAICS code 33911 (Medical Equipment and Supplies Manufacturing) are considered small. Because the final rule is not expected to impose costs on manufacturers or distributors of FDA-regulated products, the final rule is also not expected to impose costs on small entities. Therefore, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

TABLE 2—SMALL BUSINESS ADMINISTRATION SIZE STANDARDS FOR AFFECTED INDUSTRIES

NAICS code	Industry description	Small business threshold
312230	Tobacco Manufacturing	Fewer than 1,500 Employees.
325411	Medicinal and Botanical Manufacturing	Fewer than 1,000 Employees.
325412	Pharmaceutical Preparation Manufacturing	Fewer than 1,250 Employees.
325413	In-vitro Diagnostic Substance Manufacturing	Fewer than 1,250 Employees.
325414	Biological Product (except Diagnostic) Manufacturing.	Fewer than 1,250 Employees.
339112	Surgical and Medical Instrument Manufacturing	Fewer than 1,000 Employees.
339113	Surgical Appliance and Supplies Manufacturing	Fewer than 750 Employees.
339114	Dental Equipment and Supplies Manufacturing	Fewer than 750 Employees.
339115	Ophthalmic Goods Manufacturing	Fewer than 1,000 Employees.
339116	Dental Laboratories	Fewer than 500 Employees.

VIII. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(h), (i), and (k) 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.

IX. 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.

X. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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, we conclude 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.

XI. Consultation and Coordination With Indian Tribal Governments

We have analyzed this rule in accordance with the principles set forth in Executive Order 13175. We have determined that the rule does not contain policies that have substantial direct effects on one or more Indian Tribes, 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. Accordingly, we conclude that the rule does not contain policies that have tribal implications as defined in the Executive Order and, consequently, a tribal summary impact statement is not required.

XII. References

The following references are on display at the Dockets Management Staff (see **ADDRESSES**) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov*. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

1. Regulations for the Enforcement of the Federal Food, Drug, and Cosmetic Act, 17 FR 6818, 6820 (1952).
2. U.S. Department of Justice, U.S. Attorney's Office, Northern District of Georgia, ''Five Defendants Charged With Illegally Importing Male Enhancement Products,'' May 29, 2014 (available at *https://www.justice.gov/usao-ndga/pr/five-defendants-charged-illegally-importing-male-enhancement-products*).
3. Defendants' Memorandum in Support of Motion to Dismiss or for Summary Judgment and in Opposition to Motion for Preliminary Injunction at 8, *Par Pharmaceutical Inc.* v. *United States,* 1:11–cv–01820 (D.D.C. December 23, 2011).
4. Defendants' Memorandum of Points and Authorities in Support of Motion to Dismiss or for Summary Judgment at 8–9 n.5, *Allergan Inc.* v. *United States,* 1:09–cv–01879–JDB, (D.D.C. January 11, 2010).
5. Plaintiff's Motion for Summary Judgment at 20–26, *United States* v. *Undetermined Quantities of Articles of Drug, Street Drug Alternatives, Identified in Attachment A, et al.,* Civil No. AW–00–1687 (D. Md. January 12, 2001).
6. Government Trial Memorandum at 6, *United States* v. *Teiman,* Criminal No: 7:00CR00054 (W.D. Va. September 29, 2000).
7. Letter from Steven B. Barber, District Director, Cincinnati District, FDA to Marc C. Sanchez, Esq., Mood and Mind, LLC, at 9–10 (April 6, 2017).
8. Letter from Margaret M. Dotzel, Assoc. Commissioner for Policy, FDA to Daniel J. Popeo and Richard A. Samp, Wash. Legal Found., at 6, Docket No. 01P–0250 (January 28, 2002).
9. Letter from Ann Simoneau, J.D., Director, Office of Compliance and Enforcement, Center for Tobacco Products and Donald D. Ashley, J.D., Director, Office of Compliance, Center for Drug Evaluation and Research, FDA to HelloCig Electronic Technology Co., Ltd (October 11, 2018).
10. Letter from Ramon A. Hernandez, Director, San Juan District Office and Program Division Director, Office of Human and Animal Food Operations, Division IV East, FDA, to Ricardo Mayo-Alvarez, Duy Drugs, Inc. (August 28, 2018).
11. Letter from Daniel Solis, Director, Import Operations Branch, Los Angeles District to Carol A. Pratt, K&L Gates LLP (December 3, 2012).
12. Letter from Alonza E. Cruse, District Director, Los Angeles District, FDA to Richard Carieri, Lifetech Resources Labs Inc. (April 18, 2011).
13. Letter from Ronald M. Pace, District Director, New York District, FDA to Peter Erlikh, INZ Distributors, Inc. (August 23, 2010).
14. U.S. Department of Justice, ''December 2, 2016: Woman Arrested for Injecting Adulter[at]ed Liquid Silicone,'' accessed December 23, 2020, *https://www.justice.gov/usao-pr/pr/woman-arrested-injecting-adultered-liquid-silicone*.
15. U.S. Department of Justice, 2018, ''March 2, 2018: Woman Sentenced for Injecting Adulterated Liquid Silicone,'' accessed December 23, 2020, *https://www.justice.gov/usao-pr/pr/woman-sentenced-injecting-adulterated-liquid-silicone*.
16. Robertson, C.T. ''When Truth Cannot be Presumed: The Regulation of Drug Promotion Under An Expanding First Amendment,'' 94 B.U.L. REV. 545, 549–50 (2014).
17. Memorandum: Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products (January 2017) (available at *https://www.regulations.gov/document?D=FDA-2016-N-1149-0040*).

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, 21 CFR parts 201 and 801 are amended as follows:

PART 201—LABELING

■ 1. The authority citation for part 201 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 343, 351, 352, 353, 355, 358, 360, 360b, 360ccc, 360ccc–1, 360ee, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

■ 2. Revise § 201.128 to read as follows:

§ 201.128 Meaning of intended uses.

The words *intended uses* or words of similar import in §§ 201.5, 201.115, 201.117, 201.119, 201.120, 201.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of an article (or their representatives). The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for an approved drug based solely on that firm's knowledge that such drug was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

PART 801—LABELING

■ 3. The authority citation for part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 360d, 360i, 360j, 371, 374.

■ 4. Revise § 801.4 to read as follows:

§ 801.4 Meaning of intended uses.

The words *intended uses* or words of similar import in §§ 801.5, 801.119, 801.122, and 1100.5 of this chapter refer to the objective intent of the persons legally responsible for the labeling of an article (or their representatives). The intent may be shown by such persons' expressions, the design or composition of the article, or by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. Objective intent may be shown, for example, by circumstances in which the article is, with the knowledge of such persons or their representatives, offered or used for a purpose for which it is neither labeled nor advertised; provided, however, that a firm would not be regarded as intending an unapproved new use for a device approved, cleared, granted marketing authorization, or exempted from premarket notification based solely

on that firm's knowledge that such device was being prescribed or used by health care providers for such use. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he or she received the article, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses.

Dated: July 14, 2021.

Janet Woodcock,

Acting Commissioner of Food and Drugs.

Dated: July 22, 2021.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2021–15980 Filed 7–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0480]

RIN 1625–AA00

Safety Zone; Lake of the Ozarks, Mile Markers 7, 10.5, 13, 16, 22, 26, 34, and 42, Lake of the Ozarks, MO

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones in all navigable waters extending 420 feet in all directions around fireworks barges at eight different locations on the Lake of the Ozarks. These safety zones are needed to protect personnel, vessels, and the marine environment from potential hazards created by the fireworks displays. Entry of vessels or persons into these zones is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River or a designated representative.

DATES: This rule is effective on August 10, 2021 at 10 p.m. to 10:30 p.m.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0480 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Commander Stephanie Moore, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2560, email *Stephanie.R.Moore@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because it is impracticable. We must establish this safety zone by August 10, 2021 and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to the public interest because immediate action is needed to respond to the potential safety hazards associated with the fireworks displays on August 10, 2021.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sector Upper Mississippi River (COTP) has determined that potential hazards associated with the fireworks displays on August 10, 2021 will be a safety concern for anyone on the Lake of the Ozarks at the designated launch locations. This rule resulted from a marine event notification stating that there will be fireworks displays to celebrate a bicentinneal birthday on the Lake of the Ozarks. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone before, during, and after the fireworks display.

IV. Discussion of the Rule

This rule establishes safety zones on August 10, 2021 from 10 p.m. until 10:30 p.m. The safety zones will be located on all navigable waters extending 420 feet in all directions around fireworks barges at the following locations on the Lake of the Ozarks at (1) mile marker 7 (38 12′35.20″ N 92 45′02.57″ W), (2) mile marker 10.5 (38 01′21.93″ N 92 47′38.93″ W), (3) mile marker 13 (38 11′01.86″ N 92 41′19.32″ W), (4) mile marker 16 (38 08′54.89″ N 92 38′29.53″ W), (5) mile marker 22 (38 08′54.89″ N 92 41′18.95″ W), (6) mile marker 26 (38 07′25.22″ N 92 42′58.65″ W), (7) mile marker 34 (38 07′25.22″ N 92 47′34.59″ W) and (8) mile marker 42 (38 08′55″ N 92 52′23.30″ W). The duration of these zones is intended to protect personnel, vessels, and the marine environment in these navigable waters before, during, and after the fireworks displays. No vessel or person will be permitted to enter the safety zones without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Upper Mississippi River. The COTP or a designated representative will inform the public of the enforcement date and times for these safety zones, as well as any emergent safety concerns that may delay the enforcement of the zones.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and 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 approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, and duration of the temporary safety zones. This action involves fireworks displays at multiple designated locations on the

Lake of the Ozarks accuring symultaniously on August 10, 2021 and lasting 30 minutes. Vessels will be able to transit around the safety zones. Moreover, the Coast Guard will publish a Local Notice to Mariners and mariners may seek permission to enter the zones.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zones may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves safety zones lasting thirty minutes that will prohibit entry on the Lake of the Ozarks at (1) mile marker 7 (38 12′35.20″ N 92 45′02.57″ W), (2) mile marker 10.5 (38 01′21.93″ N 92 47′38.93″ W), (3) mile marker 13 (38 11′01.86″ N 92 41′19.32″ W), (4) mile marker 16 (38 08′54.89″ N 92 38′29.53″ W), (5) mile marker 22 (38 08′54.89″ N 92 41′18.95″ W), (6) mile marker 26 (38 07′25.22″ N 92 42′58.65″ W), (7) mile marker 34 (38 07′25.22″ N 92 47′34.59″ W) and (8) mile marker 42 (38 08′55″ N 92 52′23.30″ W). It is categorically excluded from further review under paragraph L60 of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. It is categorically excluded from further review under paragraph L60, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T08–0707 to read as follows:

§ 165.T08–0707 Safety Zones; Lake of the Ozarks, Mile Markers 7, 10.5, 13, 16, 22, 26, 34, 42, Lake of the Ozarks, MO

(a) *Location.* All navigable waters extending 420 feet in all directions around fireworks barges at the following locations on the Lake of the Ozarks at:

(1) Mile marker 7 (38 12′35.20″ N 92 45′02.57″ W);

(2) Mile marker 10.5 (38 01′21.93″ N 92 47′38.93″ W);

(3) Mile marker 13 (38 11′01.86″ N 92 41′19.32″ W);

(4) Mile marker 16 (38 08′54.89″ N 92 38′29.53″ W);

(5) Mile marker 22 (38 08′54.89″ N 92 41′18.95″ W);

(6) Mile marker 26 (38 07′25.22″ N 92 42′58.65″ W;

(7) Mile marker 34 (38 07′25.22″ N 92 47′34.59″ W); and

(8) Mile marker 42 (38 08′55″ N 92 52′23.30″ W).

(b) *Period of enforcement.* August 10, 2021 from 10 p.m. until 10:30 p.m.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23 of this part, persons and vessels are prohibited from entering the safety zone unless authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) Persons or vessels desiring to enter into or pass through the zone must request permission from the COTP or a designated representative. They may be contacted on VHF radio Channel 16 or by telephone at 314–269–2332.

(3) If permission is granted, all persons and vessels shall comply with the instructions of the COTP or designated representative while navigating in the regulated area.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the enforcement date and times for this safety zone, as well as any emergent safety concerns that may delay the enforcement of the zone through either A Safety Marine Information Broadcast (SMIB), Broadcast Notice to Mariners (BNM) and or Local Notices to Mariners (LNMs).

R.M. Scott,

Captain, U.S. Coast Guard, Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2021–16197 Filed 7–30–21; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2021–0584]

RIN 1625–AA00

Temporary Safety Zone; Loveless Wedding Fireworks, Omena, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for a fireworks display off the shore of the Omena Traverse Yacht Club in Omena, MI. The safety zone is needed to protect personnel, vessels, and the marine environment from potential hazards created by fireworks display. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sault Sainte Marie or a designated representative.

DATES: This rule is effective from 6 p.m. through 11:59 p.m. on August 21, 2021. It will be enforced from 9 p.m. through 11 p.m. on that day.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2021–0584 in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email LT Deaven Palenzuela, U.S. Coast Guard Sector Sault Sainte Marie Waterways Management, U.S. Coast Guard; telephone 906–635–3223, email *ssmprevention@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR Code of Federal Regulations
DHS Department of Homeland Security
FR Federal Register
NPRM Notice of proposed rulemaking
§ Section
U.S.C. United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The event sponsor did not submit notice to the Coast Guard with sufficient time to publish an NPRM and receive public comments prior to the event. Delaying the effective date of this rule to wait for a comment period to run would be contrary to the public interest and impractical by inhibiting the Coast Guard's ability to protect the public from the dangers associated with a fireworks display with a potential blast zone and expected fall-out area occurring over the water.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because action is needed to establish a safety zone in order to protect the public from the hazards associated with the fireworks display.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231). The Captain of the Port Sault Sainte Marie (COTP) has determined that potential hazards associated with a fireworks display on August 21, 2021, will be a safety concern for anything within a 250-foot radius of the navigable waters surrounding the fireworks launch site. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone during the fireworks display.

IV. Discussion of the Rule

This rule establishes a temporary safety zone that will be enforced from 9 p.m. through 11 p.m. on August 21, 2021. The safety zone will cover all navigable waters within 250 feet of a fireworks display off shore Omena Traverse Yacht Club in Omena, MI in position 45°6′6.36″ N 85°34′48.22″ W. The duration of the zone is intended to protect personnel, vessels, and the marine environment in the safety zone proceeding, during and immediately after the fireworks display.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and 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 approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on size, location, duration, and time-of-day of the safety zone. Vessel traffic will be able to safely transit around this safety zone which would impact a small designated area off shore of Omena Traverse Yacht Club.

Moreover, the Coast Guard would issue a Broadcast Notice to Mariners via VHF–FM marine channel 16 about the zone.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term ''small entities'' comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the safety zone may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969(42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a temporary safety zone lasting only 2 hours that will prohibit entry within a 250-foot radius of a fireworks display off shore Omena Traverse Yacht Club in Omena, MI. It is categorically excluded from further review under paragraph L[60(a)] of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 46 U.S.C. 70034, 70051; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T09–0584 to read as follows:

§ 165.T09–0584 Loveless Wedding Fireworks, Off Shore Omena Traverse Yacht Club, Omena, MI.

(a) *Location.* The following area is a temporary safety zone: All navigable water within 250 feet of the fireworks launching location in position 45°3′6.36″ N 85°34′48.22″ W (NAD 83)

(b) *Definitions.* As used in this section, designated representative means a Coast Guard Patrol Commander, including a Coast Guard coxswain, petty officer, or other officer operating a Coast Guard vessel and a Federal, State, and local officer designated by or assisting the Captain of the Port Sault Sainte Marie (COTP) in the enforcement of the safety zone.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within the safety zone described in paragraph (a) of this section is prohibited unless authorized by the Captain of the Port, Sault Sainte Marie or his designated representative.

(2) Before a vessel operator may enter or operate within the safety zone, they must obtain permission from the Captain of the Port, Sault Sainte Marie, or his designated representative via VHF Channel 16 or telephone at (906) 635–3233. Vessel operators given permission to enter or operate in the safety zone must comply with all orders given to them by the Captain of the Port, Sault

Sainte Marie or his designated representative.

(d) *Enforcement period.* This section will be enforced from 9 p.m. through 11 p.m. on August 21, 2021.

Dated: July 26, 2021.

A.R. Jones,

Captain of the Port Sault Sainte Marie.

[FR Doc. 2021–16214 Filed 7–30–21; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2021–0334; FRL–8706–02–R7]

Air Plan Approval; Missouri; Restriction of Emissions From Lithographic and Letterpress Printing Operations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a State Implementation Plan (SIP) revision submitted by the State of Missouri on November 10, 2020. This final action will amend the SIP to revise a Missouri regulation which restricts volatile organic compound emissions from lithographic and letterpress printing operations in the St. Louis Metropolitan Area. Specifically, the State has revised this rule in order to clarify rule applicability, update incorporation by reference information, update test method references, clarify definitions, and remove unnecessary words to improve clarity. Approval of these revisions will ensure consistency between State and federally-approved rules.

DATES: This final rule is effective on September 1, 2021.

ADDRESSES: The EPA has established a docket for this action under Docket ID No. EPA–R07–OAR–2021–0334. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *i.e.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *https://www.regulations.gov* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional information.

FOR FURTHER INFORMATION CONTACT: Larry Gonzalez, Environmental Protection Agency, Region 7 Office, Air Quality Planning Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219; telephone number: (913) 551–7041; email address: *gonzalez.larry@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document ''we,'' ''us,'' and ''our'' refer to EPA.

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I. What is being addressed in this document?
II. Have the requirements for approval of a SIP revision been met?
III. What action is the EPA taking?
IV. Incorporation by Reference
V. Statutory and Executive Order Reviews

I. What is being addressed in this document?

The EPA is approving revisions to the Missouri SIP received on November 10, 2020. The revisions are to Title 10, Division 10 of the Code of State Regulations, 10 CSR 10–5.442 ''Control of Emissions From Lithographic and Letterpress Printing Operations'', which establishes emission limits for volatile organic compounds (VOCs) from lithographic and letterpress printing operations in St. Louis City and Jefferson, Franklin St. Louis, and St. Charles Counties (hereinafter referred to in this document as the ''St. Louis Area''). The provision at 10 CSR 10–5.442 is SIP approved in the Code of Federal Regulations at 40 CFR 52.1320(c).

These revisions, as discussed in section IV of the EPA's proposed rule, and the technical support document (TSD) in the docket for the proposed rule, are largely administrative in nature and do not have a negative impact on air quality (86 FR 27543, May 21, 2021).

The public comment period on the EPA's proposed rule opened May 21, 2021, the date of its publication in the **Federal Register** and closed on June 21, 2021. During this period, the EPA received no comments. The EPA is finalizing approval the revisions to this rule because it meets the requirements of the Clean Air Act and will not have a negative impact on air quality.

II. Have the requirements for approval of a SIP revision been met?

The State's submission has met the public notice requirements for SIP submissions in accordance with 40 CFR 51.102. The submission also satisfied the completeness criteria of 40 CFR part 51, appendix V. The State provided public notice of the revisions from May 1, 2019, to August 1, 2019, and held a public hearing on July 25, 2019. The State received and addressed five comments (four being from the EPA). As explained in more detail in the TSD which is part of this docket, the SIP revision submission meets the substantive requirements of the Clean Air Act (CAA), including section 110 and implementing regulations.

III. What action is the EPA taking?

The EPA is taking final action to amend the Missouri SIP by approving the State's request to revise 10 CSR 10–5.442, ''Control of Emissions From Lithographic and Letterpress Printing Operations.'' Approval of these revisions will ensure consistency between State and federally-approved rules. The EPA has determined that these changes meet the requirements of the Clean Air Act and will not have a negative impact to air quality.

IV. Incorporation by Reference

In this document, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with the requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of the Missouri Regulations described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 7 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

Therefore, these materials have been approved by the EPA for inclusion in the State Implementation Plan, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of the EPA's approval, and will be incorporated by reference in the next update to the SIP compilation.[1]

V. Statutory and Executive Order Reviews

Under the Clean Air Act (CAA), 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 CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements

[1] 62 FR 27968, May 22, 1997.

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 Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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 the National Technology Transfer and Advancement Act (NTTA) because this rulemaking does not involve technical standards; 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, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action 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**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 1, 2021. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Volatile organic compounds.

Dated: July 22, 2021.

Edward H. Chu,

Acting Regional Administrator, Region 7.

For the reasons stated in the preamble, EPA amends 40 CFR part 52 as set forth below:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart AA—Missouri

■ 2. In § 52.1320, the table in paragraph (c) is amended by revising entry ''10–5.442'' to read as follows:

§ 52.1320 Identification of plan.

* * * * *

(c) * * *

EPA-APPROVED MISSOURI REGULATIONS

Missouri citation	Title	State effective date	EPA approval date	Explanation
Missouri Department of Natural Resources				
*	*	*	*	*
Chapter 5—Air Quality Standards and Air Pollution Control Regulations for the St. Louis Metropolitan Area				
*	*	*	*	*
10–5.442	Control of Emissions from Lithographic and Letterpress Printing Operations.	01/30/2020	8/2/2021, [insert **Federal Register** citation].	
*	*	*	*	*

* * * * *

[FR Doc. 2021–16218 Filed 7–30–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket No. 21–93; DA 21–881; FR ID 40821]

Wireline Competition Bureau Sets Service Delivery Date for Emergency Connectivity Fund Program Initial Application Filing Window and Modifies Funding Application Certification Language

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Wireline Competition Bureau (Bureau) establishes a June 30, 2022, service delivery date for equipment and other non-recurring services funding requests filed during the initial application filing window of the Emergency Connectivity Fund Program, if the equipment or services have not been received at the time the funding request is made. The Bureau also modifies the certification language of the Commission's rules to clarify that applicants may request funding for eligible equipment and services that have not yet been ordered for the upcoming school year (*i.e.,* July 1, 2021 through June 30, 2022).

DATES: Effective August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Johnnay Schrieber, Wireline Competition Bureau, (202) 418–7400 or by email at *Johnnay.Schrieber@fcc.gov.* The Commission asks that requests for accommodations be made as soon as possible in order to allow the agency to satisfy such requests whenever possible. Send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Public Notice in WC Docket No. 21–93; DA 21–881, released July 22,2021. Due to the COVID–19 pandemic, the Commission's headquarters will be closed to the general public until further notice. The full text of this document is available at the following internet address: *https://www.fcc.gov/edocs/search-results?t=quick&fccdaNo=21-881.*

SYNOPSIS

1. By this Public Notice, the Wireline Competition Bureau (Bureau) establishes a June 30, 2022 service delivery date for equipment and other non-recurring services funding requests filed during the initial application filing window of the Emergency Connectivity Fund Program, if the equipment or services have not been received at the time the funding request is made. The Bureau also modifies the certification language for § 54.1710(a)(1)(x) of the Commission's rules to clarify that applicants may request funding for eligible equipment and services that have not yet been ordered for the upcoming school year (*i.e.,* July 1, 2021 through June 30, 2022).

2. As part of the American Rescue Plan Act of 2021, Congress appropriated $7.171 billion to the Federal Communications Commission (Commission) to promulgate rules providing for the distribution of funding from the Emergency Connectivity Fund to eligible schools and libraries for the purchase of eligible equipment and/or advanced telecommunications and information services for use by students, school staff, and library patrons at locations that include locations other than a school or library. On May 10, 2021, the Commission issued a *Report and Order,* 86 FR 29136, May 28, 2021, establishing the Emergency Connectivity Fund Program to administer the $7.171 billion in congressionally appropriated funding. The Commission and the Universal Service Administrative Company (USAC) opened a 45-day Emergency Connectivity Fund application filing window on June 29, 2021, which will close on August 13, 2021. During this initial filing window, applicants may request funding for eligible equipment and services that will be received or delivered between July 1, 2021, and June 30, 2022.

3. *Service Delivery Date.* The Commission established an invoice filing deadline rule for the Emergency Connectivity Fund Program in the *Report and Order.* Section 54.1711(d) provides that ''[i]nvoices must be submitted to the Administrator within 60 days from the date of the funding commitment decision letter; a revised funding commitment decision letter approving a post-commitment change or a successful appeal of previously denied or reduced funding; or service delivery date, whichever is later.'' However, for non-recurring services or equipment to be funded through the initial window of the Emergency Connectivity Fund Program, the service delivery date may not be known at the time the applicant submits the funding request. In order to streamline and simplify the application and invoicing processes, and pursuant to the Bureau's authority to provide additional detail and specificity to the requirements of the Emergency Connectivity Fund Program in consultation with the Office of the Managing Director, and for purposes of establishing the deadline for the submission of invoices, the Bureau establishes June 30, 2022, as the service delivery date for equipment and other non-recurring services funding requests if the equipment or services have not been ordered or received when the applicant submits the funding request. As such, applicants may use June 30, 2022, as the ''service end date'' in the funding request where indicated in the Emergency Connectivity Fund Program application portal, and the invoicing deadline for these non-recurring services and equipment will be 60 days from the date of the funding commitment decision letter; a revised funding commitment decision letter approving a post-commitment change or a successful appeal of previously denied or reduced funding; or August 29, 2022 (*i.e.,* 60 days after June 30, 2022), whichever is later. Adopting a uniform service delivery date for equipment and other non-recurring services will provide certainty for these applicants and allow USAC to provide an invoice filing deadline to applicants at the time it provides the funding commitment letter.

4. *Clarification to Section 54.1710(a)(1)(x).* In the *Report and Order,* the Commission adopted, and codified at § 54.1710(a)(1), the certifications that applicants must include on their funding applications. Section 54.1710(a)(1)(x) requires applicants to certify that ''[t]he applicant or the relevant student, school staff member, or library patron has received, or the applicant has ordered the equipment and services for which funding is sought.'' As explained above, the current Emergency Connectivity Fund Program application filing window is for prospective purchases of eligible equipment and services made between July 1, 2021, and June 30, 2022. Therefore, it is possible that applicants may not have ordered the requested equipment and services at the time they are submitting their applications for funding through the Emergency Connectivity Fund Program. To address this circumstance, the Bureau modifies § 54.1710(a)(1)(x) to require applicants to certify that: ''[t]he applicant or the relevant student, school staff member, or library patron has received, or the applicant has ordered or will order, the equipment and services for which funding is sought.'' This clarification conforms the certification to the

requirement set forth in the *Report and Order* that eligible equipment and services funded through the initial application filing window must be provided or delivered between July 1, 2021, and June 30, 2022, and permits the certification required by the applicant or service provider at the invoicing stage that the equipment and services have been received or ordered.

5. These two procedural rule changes for the Emergency Connectivity Fund Program, and the updated rules will become effective upon publication in the **Federal Register**.

6. *Additional Information.* For more information about the Emergency Connectivity Fund Program, please refer to the Commission's website at *https://www.fcc.gov/emergency-connectivity-fund.*

List of Subjects in 47 CFR Part 54

Communications common carriers, internet, Libraries, Reporting and recordkeeping requirements, Schools, Telecommunications

Federal Communications Commission

Cheryl Callahan,

Assistant Chief, Telecommunications Access Policy Division, Wireline Competition Bureau.

Final Rules

For the reasons set forth above, part 54 of title 47 of the Code of Federal Regulations is amended as follows:

PART 54—UNIVERSAL SERVICE

■ 1. The authority for part 54 continues to read as follows:

Authority: 47 U.S.C. 151, 154(i), 155, 201, 205, 214, 219, 220, 229, 254, 303(r), 403, 1004, 1302, and 1601–1609, unless otherwise noted.

■ 2. Amend § 54.1710 by revising paragraph (a)(1)(x) to read as follows:

§ 54.1710 Emergency Connectivity Fund requests for funding.

(a) * * *

(1) * * *

(x) The applicant or the relevant student, school staff member, or library patron has received, or the applicant has ordered or will order, the equipment and services for which funding is sought.

* * * * *

■ 3. Amend § 54.1711 by adding paragraph (e) to read as follows:

§ 54.1711 Emergency Connectivity Fund requests for reimbursement.

* * * * *

(e) *Service delivery date.* For the initial filing window set forth in § 54.1708(b), the service delivery date for equipment and other non-recurring services if the equipment or services have not been received or ordered when the applicant submits the request for funding is June 30, 2022.

[FR Doc. 2021–16361 Filed 7–30–21; 8:45 am]

BILLING CODE 6712–01–P

Proposed Rules

Federal Register
Vol. 86, No. 145
Monday, August 2, 2021

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 TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2020–1077; Project Identifier MCAI–2020–00819–A]

RIN 2120–AA64

Airworthiness Directives; Embraer S.A. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: The FAA proposes to adopt a new airworthiness directive (AD) for certain Embraer S.A. Models EMB–500 and EMB–505 airplanes. This proposed AD was prompted by a report that the operational envelope does not contain airspeed limitations and procedures for operating the airplane at static air temperatures below −54 °C. This proposed AD would require revising the airplane flight manual (AFM) to incorporate new and revised airspeed limitations and procedures. The FAA is proposing this AD to address the unsafe condition on these products.

DATES: The FAA must receive comments on this NPRM by September 16, 2021.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* (202) 493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Phenom Maintenance Support, Avenida Brigadeiro Faria Lima, 2170, P.O. Box 36/2, São José dos Campos, 12227–901, Brazil; phone: +55 12 3927 1000; email: *phenom.reliability@embraer.com.br;* website: *https://www.embraer.com.br/en-US/Pages/home.aspx.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 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 at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1077; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this NPRM, the mandatory continuing airworthiness information (MCAI), any comments received, and other information. The street address for Docket Operations is listed above.

FOR FURTHER INFORMATION CONTACT: Jim Rutherford, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under **ADDRESSES**. Include ''Docket No. FAA–2020–1077; Project Identifier MCAI–2020–00819–A'' at the beginning of your comments. The most helpful comments reference a specific portion of the proposal, explain the reason for any recommended change, and include supporting data. The FAA will consider all comments received by the closing date and may amend the proposal because of those comments.

Except for Confidential Business Information (CBI) as described in the following paragraph, and other information as described in 14 CFR 11.35, the FAA will post all comments received, without change, to *https://www.regulations.gov,* including any personal information you provide. The agency will also post a report summarizing each substantive verbal contact received about this NPRM.

Confidential Business Information

CBI is commercial or financial information that is both customarily and actually treated as private by its owner. Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), CBI is exempt from public disclosure. If your comments responsive to this NPRM contain commercial or financial information that is customarily treated as private, that you actually treat as private, and that is relevant or responsive to this NPRM, it is important that you clearly designate the submitted comments as CBI. Please mark each page of your submission containing CBI as ''PROPIN.'' The FAA will treat such marked submissions as confidential under the FOIA, and they will not be placed in the public docket of this NPRM. Submissions containing CBI should be sent to Jim Rutherford, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106. Any commentary that the FAA receives which is not specifically designated as CBI will be placed in the public docket for this rulemaking.

Background

The Agência Nacional de Aviação Civil (ANAC), which is the aviation authority for Brazil, has issued ANAC AD 2020–05–03, effective June 1, 2020 (ANAC AD 2020–05–03) (also referred to after this as ''the MCAI''), to correct an unsafe condition on Embraer S.A. Models EMB–500 and EMB–505 airplanes with certain engines installed. Although the affected airplanes were designed for operation at temperatures below −54 °C, the operational envelope in the AFM does not contain the necessary limitations and procedures to operate safely in these colder temperatures. The MCAI states that operation of the affected airplanes at static air temperatures below −54 °C without these limitations could cause several systems and components to operate inadequately, resulting in multiple systems failures.

Accordingly, the MCAI requires updating the AFM to incorporate a modified operational envelope that establishes restrictions and minimum airspeed required for each static temperature range. The FAA is

proposing this AD to prevent inadequate operation below the allowable temperature, which could result in multiple systems failures and compromise safe flight of the airplane.

You may examine the MCAI in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1077.

Related Service Information Under 1 CFR Part 51

The FAA reviewed Embraer Phenom Operational Bulletin No. 500–001/20, dated March 9, 2020; and Operational Bulletin No. 505–005/13, Revision 1, dated March 9, 2020. This service information specifies revising the AFM to incorporate limitations and procedures for the minimum airspeed in the affected region of the operational envelope. These documents are distinct since they apply to different airplane models. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

This product has been approved by the aviation authority of another country and is approved for operation in the United States. Pursuant to the FAA's bilateral agreement with the State of Design Authority, it has notified the FAA of the unsafe condition described in the MCAI and service information referenced above. The FAA is issuing this NPRM after determining the unsafe condition described previously is likely to exist or develop on other products of the same type design.

Proposed AD Requirements in This NPRM

This proposed AD would require revising the AFM by accomplishing the actions specified in the service information already described.

Costs of Compliance

The FAA estimates that this AD, if adopted as proposed, would affect 590 airplanes of U.S. registry. The FAA estimates the following costs to comply with this proposed AD:

ESTIMATED COSTS FOR REVISING THE AFM

Labor cost	Parts cost	Cost per product	Cost on U.S. operators
.5 work-hour × $85 per hour = $42.50	$0	$42.50	$25,075

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.

The FAA is 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

The FAA determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would 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 this proposed regulation:

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

(2) Would not affect intrastate aviation in Alaska, and

(3) Would 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.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 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 adding the following new airworthiness directive:

Embraer S.A.: Docket No. FAA–2020–1077; Project Identifier MCAI–2020–00819–A.

(a) Comments Due Date

The FAA must receive comments on this airworthiness directive (AD) by September 16, 2021.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Embraer S.A. Models EMB–500 and EMB–505 airplanes, all serial numbers, certificated in any category, with Model PW617F–E or PW617F1–E engines (for Model EMB–500 airplanes) or Model PW535E engines (for Model EMB–505 airplanes) installed.

(d) Subject

Joint Aircraft System Component (JASC) Code 0200, Operations.

(e) Unsafe Condition

This AD was prompted by a report that the operational envelope does not contain airspeed limitations and procedures for operating the airplane at static air temperatures below −54 °C. The FAA is issuing this AD to prevent inadequate operation below the allowable temperature. The unsafe condition, if not addressed, could result in multiple systems failures and compromise safe flight of the airplane.

(f) Compliance

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

(g) Revision of the Airplane Flight Manual (AFM)

Within 30 days after the effective date of this AD:

(1) For Model EMB–500 airplanes: Revise Section 2 Limitations and Section 5 Performance of the existing AFM for your airplane by incorporating the information in ''V—OPERATING INFORMATION,'' of Embraer Phenom Operational Bulletin No. 500–001/20, dated March 9, 2020.

(2) For Model EMB–505 airplanes: Revise Section 2 Limitations, Section 5 Performance, and Supplement 2 of the existing AFM for your airplane by incorporating the

information in ''V—OPERATING INFORMATION,'' of Embraer Phenom Operational Bulletin No. 505–005/13, Revision 1, dated March 9, 2020.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, International Validation Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send your request to the person identified in Related Information or email: *9-AVS-AIR-730-AMOC@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspection, the manager of the local Flight Standards District Office.

(i) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Agência Nacional de Aviação Civil AD 2020–05–03, effective June 1, 2020, for related information. This MCAI may be found in the AD docket at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2020–1077.

(2) For more information about this AD, contact Jim Rutherford, Aviation Safety Engineer, FAA, General Aviation & Rotorcraft Section, International Validation Branch, 901 Locust, Room 301, Kansas City, MO 64106; phone: (816) 329–4165; fax: (816) 329–4090; email: *jim.rutherford@faa.gov.*

(3) For service information identified in this AD, contact Phenom Maintenance Support, Avenida Brigadeiro Faria Lima, 2170, P.O. Box 36/2, São José dos Campos, 12227–901, Brazil; phone: +55 12 3927 1000; email: *phenom.reliability@embraer.com.br;* website: *https://www.embraer.com.br/en-US/Pages/home.aspx.* You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 901 Locust, Kansas City, MO 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued on July 27, 2021.

Lance T. Gant,

Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–16339 Filed 7–30–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2021–0537; Airspace Docket No. 21–ASO–21]

RIN 2120–AA66

Proposed Amendment of Class E Airspace; Mooresville, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to amend Class E airspace extending upward from 700 feet above the surface for Lake Norman Airpark, Mooresville, NC, by removing Lowe's Mooresville Heliport from the description, as the heliport has closed and airspace is no longer required. This action would enhance the safety and management of controlled airspace within the national airspace system. Also, during the airspace review the FAA determined a radius increase was required at Lake Norman Airpark. In addition, the FAA proposes to remove unnecessary verbiage that references Class E airspace in Statesville, NC, and Concord, NC. Controlled airspace is necessary for the safety and management of instrument flight rules (IFR) operations in the area.

DATES: Comments must be received on or before September 16, 2021.

ADDRESSES: Send comments on this proposal to: The U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001; Telephone: (800) 647–5527 or (202) 366–9826. You must identify the Docket No. FAA–2021–0537; Airspace Docket No. 21–ASO–21, at the beginning of your comments. You may also submit comments through the internet at *https://www.regulations.gov.*

FAA Order 7400.11E Airspace Designations and Reporting Points, and subsequent amendments, can be viewed online at *https://www.faa.gov/air_traffic/publications/.* For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591; Telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.11E at NARA, email *fedreg.legal@nara.gov* or go to *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

FOR FURTHER INFORMATION CONTACT: John Goodson, Operations Support Group, Eastern Service Center, Federal Aviation Administration, 1701 Columbia Avenue, College Park, GA 30337; Telephone (404) 305–5966.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. 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. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority, as it would amend Class E airspace in Mooresville, NC to support IFR operations in the area.

Comments Invited

Interested persons are invited to comment on this proposed rulemaking by submitting such written data, views, or arguments, as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (Docket No. FAA–2021–0537 and Airspace Docket No. 21–ASO–21) and be submitted in triplicate to DOT Docket Operations (see **ADDRESSES** section for the address and phone number). You may also submit comments through the internet at *https://www.regulations.gov.*

Persons wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2021–0537; Airspace Docket No. 21–ASO–21.'' The postcard will be date/time stamped and returned to the commenter.

All communications received before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this document may be changed in light of the comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *https://www.regulations.gov.* Recently published rulemaking documents can also be accessed through

the FAA's web page at *https://www.faa.gov/air_traffic/publications/airspace_amendments/.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see the **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except federal holidays. An informal docket may also be examined between 8:00 a.m. and 4:30 p.m., Monday through Friday, except federal holidays, at the office of the Eastern Service Center, Federal Aviation Administration, Room 350, 1701 Columbia Avenue, College Park, GA 30337.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020 and effective September 15, 2020. FAA Order 7400.11E is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.11E lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA proposes an amendment to 14 CFR part 71 to amend Class E airspace extending upward from 700 feet above the surface at Lake Norman Airpark, Mooresville, NC, by removing Lowe's Mooresville Heliport from the description, as the heliport has closed and airspace is no longer required. This action would enhance the safety and management of controlled airspace within the national airspace system. Also, the radius of the Lake Norman Airpark would increase to 9.3 miles (previously 6.3 Miles). In addition, the FAA proposes to remove the unnecessary verbiage in the description referencing Class E airspace in Statesville, NC and Concord, NC.

Class E airspace designations are published in Paragraph 6005 of FAA Order 7400.11E, dated July 21, 2020 and effective September 15, 2020, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

FAA Order 7400.11, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (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); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, ''Environmental Impacts: Policies and Procedures'', prior to any FAA final regulatory action.

Lists of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.11E, Airspace Designations and Reporting Points, dated July 21, 2020, and effective September 15, 2020, is amended as follows:

Paragraph 6005 Class E Airspace Areas Extending Upward From 700 Feet or More Above the Surface of the Earth.

* * * * *

ASO NC E5 Mooresville, NC [Amended]

Lake Norman Airpark, NC
(Lat. 35°36′50″ N, long. 80°53′58″ W)

That airspace extending upward from 700 feet above the surface within a 9.3-radius of Lake Norman Airpark.

Issued in College Park, Georgia, on July 27, 2021.

Andreese C. Davis,

Manager, Airspace & Procedures Team South, Eastern Service Center, Air Traffic Organization.

[FR Doc. 2021–16346 Filed 7–30–21; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2021–0433; FRL–8683–01–R8]

Approval and Promulgation of Implementation Plans; North Dakota; Revisions To Permitting Regulations Unrelated to Regional Haze

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: In accordance with section 110 of the Clean Air Act (CAA), the Environmental Protection Agency (EPA) is proposing to approve State Implementation Plan (SIP) revisions submitted by North Dakota on August 3, 2020. The revisions contain amendments to the State's Air Pollution Control Regulations and to the State's Legal Authority.

DATES: Written comments must be received on or before September 1, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R08–OAR–2021–0433, to the Federal Rulemaking Portal: *https://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *www.regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, the full

EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

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 electronically in *www.regulations.gov.* To reduce the risk of COVID–19 transmission, for this action we do not plan to offer hard copy review of the docket. Please email or call the person listed in the **FOR FURTHER INFORMATION CONTACT** section if you need to make alternative arrangements for access to the docket.

FOR FURTHER INFORMATION CONTACT: Kevin Leone, Air and Radiation Division, EPA, Region 8, Mailcode 8ARD–IO, 1595 Wynkoop Street, Denver, Colorado 80202–1129, telephone number: (303) 312–312–6227, email address: *leone.kevin@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document wherever ''we,'' ''us,'' or ''our'' is used, we mean the EPA.

I. Background

On August 3, 2020, the State of North Dakota submitted SIP revisions containing amendments to North Dakota Administrative Code (NDAC), Article 33.1–15 (Air Pollution Control) located in North Dakota's EPA-Approved Regulations. Article 33.1–15 consists of 25 chapters numbered from 33.1–15–01 through 33.1–15–25. Revisions to 33.1–15–25 (Regional Haze Requirements) were acted on in a separate rulemaking.[1] North Dakota is also revising section 2.15 (Respecting Boards) located in North Dakota's EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures. These revisions became effective as a matter of State law on July 1, 2020. We are proposing to approve these revisions, except for the previously approved regional haze provisions.

[1] The EPA approved North Dakota's rule revisions to chapter 33.1–15–25 (regional haze) on June 8, 2021 (86 FR 30387).

II. The EPA's Evaluation

A. Revisions to Chapter 33.1–15–01 (General Provisions)

(1) Section 33.1–15–01–01 (Purpose)

* Line 3—A semicolon is added after the word ''property.''

This revision is approvable, as it is administrative in nature.

(2) Section 33.1–15–01–04 (Definitions)

* In Section 33.1–15–01–04–04.45, a comma is added after ''emission.''

This revision is approvable, as it is administrative in nature.

* In Section 33.1–15–01–04–04.52, the date for incorporation by reference for the definition of ''volatile organic compounds'' (VOC's) is changes from July 1, 2015 to July 1, 2019.

This revision is approvable, as it keeps North Dakota's definition current with the federal definition of VOCs. North Dakota's regulation located in section 33.1–15–01–04–04.52 states:

> ''Volatile Organic Compounds'' means the definition of volatile organic compounds in 40 Code of Federal Regulations 51.100(s) as it exists on July 1, 2015, which is incorporated by reference.''

This revision reflects the current EPA definition of VOCs in 40 CFR 51.100(s), which was last revised by the EPA on November 28, 2018 (83 FR 61127). In addition, North Dakota incorporates by reference 40 CFR 52.21 for their Prevention of Significant Deterioration (PSD) regulations. The definition of VOCs located in 40 CFR 52.21(a)(30) states:

> ''Volatile organic compounds (VOC) is as defined in 40 CFR 51.100(s) of this chapter.''

As such, this revision also keeps North Dakota's PSD regulation of VOCs current with the federal definition of VOCs.

(3) Section 33.1–15–01–05 (Abbreviations)

* For the abbreviation of Abbreviation of PM_{10}, the words ''a nominal'' are added.

This revision is approvable, as it is administrative in nature.

B. Revisions to Chapter 33.1–15–02 (Ambient Air Quality Standards, Table 1)

(1) Table 1

* In Table 1, for fine particulates ($PM_{2.5}$) the determination of compliance is being clarified by adding the phrase ''three-year average'' to the annual standard and the phrase ''three-year average of the annual'' is added to the 24-hour standard.

These revisions are approvable, as this language corresponds with the language found in 40 CFR part 50, appendix N (Interpretation of the National Ambient Air Quality Standards for $PM_{2.5}$.). Appendix N states the data handling necessary for determining when the National Ambient Air Quality Standards (NAAQS) for $PM_{2.5}$ are met, specifically for the primary and secondary annual and 24-hour $PM_{2.5}$ NAAQS specified in 40 CFR 50.7, 50.13 and 50.18.

Appendix N states that there are two separate design values (DVs) for determining compliance with the NAAQS. Design values are the 3-year average NAAQS metrics which are compared to the NAAQS levels to determine which monitoring site meets or does not meet the NAAQS. Appendix N specifies two separate DVs:

(1) The 3-year average of $PM_{2.5}$ annual mean mass concentrations for each monitoring site; and

(2) The 3-year average of annual 98th percentile 24-hour average.

(2) Table 1

* In Table 1, North Dakota is revising its maximum permissible concentration for ozone from 0.075 parts per million (ppm) to 0.070 ppm.

This revision is approvable. In 2015, the EPA promulgated a revised ozone NAAQS of 0.070 parts per million (ppm). (See Final Rule, National Ambient Air Quality Standard for Ozone, 80 FR 65292, October 26, 2015.) This rulemaking revised the maximum permissible concentration for ozone to 0.070 ppm. When a new or revised NAAQS is promulgated, the CAA requires each state to submit a SIP revision to incorporate the new standard. North Dakota revised Table 1 to reflect the 2015 ozone NAAQS of 0.070 ppm.

C. Revisions to Chapter 33.1–15–03 (Restriction of Emission of Visible Air Contaminants)

* The title of the chapter is being revised to remove an ''m'' from ''emissions.''

This revision is approvable, as it is administrative in nature.

D. Revisions to Chapter 33.1–15–14 (Designated Air Contaminant Sources, Permit To Construct, Minor Source Permit To Operate, Title V Permit To Operate)

(1) Section 33.1–15–14–01.1.2h

* In paragraph 33.1–15–14–01.1.2h, the word ''onsite'' is added twice.

This revision is approvable as it is administrative in nature.

(2) Section 33.1–15–14–02.4a

* In subdivision 33.1–15–14–02.4a, the date for incorporation by reference of PSD modeling guidance by referring to 40 CFR part 51, appendix W (Guideline on Air Quality Models) as it existed on July 1, 2019, and the reference to the North Dakota Modeling Guidance is deleted.

This revision is approvable, as the State is adopting federal guidelines for determining the effects on ambient air quality related to an application for a permit to construct, and this revision deletes the State's own guidance on air quality modeling.

(3) Chapter 33–15–14–02.5

* In subsection 33.1–15–14–02.5, line 2, the word ''an'' is added before application.

This revision is approvable, as it is administrative in nature.

(4) Chapter 33.1–15–14–02.5a

* In the subdivision 33.1–15–14–02.5a, the significant impact level (SIL) for annual $PM_{2.5}$ emissions is revised to 0.2 micrograms per cubic meter, and a SIL for 8-hour ozone of 2.0 micrograms per cubic meter is added.

These revisions are approvable. On October 20, 2010, the EPA promulgated a final rulemaking titled ''Prevention of Significant Deterioration (PSD) for Particulate Matter Less than 2.5 micrometers—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentrations (SMCs),'' (75 FR 64864). This rulemaking revised the SIL for the annual $PM_{2.5}$ to 0.3 micrograms per cubic meter for Class II and Class III areas, and 0.06 micrograms per cubic meter for Class I areas.

However, on December 17, 2010, the Sierra Club petitioned the Court to review the 2010 $PM_{2.5}$ SILs and SMC final rule. On January 22, 2013, the Court granted a request from the EPA to vacate and remand to the EPA portions of the PSD regulations (40 CFR 51.166(k)(2) and 52.21(k)(2)) establishing the SILs for $PM_{2.5}$ so that the EPA could reconcile the inconsistency between the regulatory text and certain statements in the preamble to the 2010 final rule. *Sierra Club* v. *EPA*, 705 F.3d 458, 463–64 (D.C. Cir. 2013). As a result, on December 9, 2013, EPA issued a final rule that removes the $PM_{2.5}$ SILs from EPA's PSD regulations ($PM_{2.5}$ Vacated Elements rulemaking). On April 17, 2018, the EPA issued a guidance memo titled ''Guidance on Significant Impact Levels for Ozone and Fine Particles in the Prevention of Significant Deterioration Permitting Program'' (See docket), which provided guidance on compliance demonstration tools for use with ozone and $PM_{2.5}$ in the PSD program. This guidance can be used to identify a SIL for each ozone and $PM_{2.5}$ NAAQS. Permitting authorities may use these values to help determine whether a proposed PSD source causes or contributes to a violation of the corresponding NAAQS. The guidance recommends a SIL of 0.2 micrograms per cubic meter for annual $PM_{2.5}$ and a SIL of 1.0 parts per billion (pbb) for 8-hour ozone. North Dakota's new SIL for 8-hour ozone is 2.0 micrograms per cubic meter, which converts to one pbb (see docket for conversion).

(5) Chapter 33.1–15–14–02.8

* In subsection 33.1–15–14–02.8, line 3, the word ''or'' is being changed to ''and.''

This revision is approvable, as it is requiring an affirmative review of the requirements in both subsection 5(a) and 5(b) of this subsection before granting a permit to construct, as opposed to one or the other. Subsection 5(a) and 5(b) contain requirements pertaining to the department's review of an application for a permit to construct.

E. Revisions to Chapter 33.1–15–15 (Prevention of Significant Deterioration of Air Quality)

(1) Chapter 33.1–15–01.2

* In section 33.1–15–01.2, the date for incorporation by reference is updated to July 1, 2019. In addition, the phrase ''or the administrator's authorized representative'' is added.

This revision is approvable, as it expands the definition of ''administrator of the United States environmental protection agency'' to include ''or the administrator's authorized representative.''

(2) Chapter 33.1–15–01.2(q)

* In section 33.1–15–01.2(q), public participation, paragraph (q)(2)(c) is being revised to add the phrase ''and by a notice on the department's website.''

This phrase is approvable, as it is in compliance with the requirements in 40 CFR 52.21(q), which states:

''The administrator shall follow the applicable procedures of 40 CFR part 124 in processing applications under this section.''

40 CFR part 124(xi)(2)(iii) outlines the requirements as it relates to publishing PSD permits for the duration of the public comment period. 40 CFR part 124(xi)(2)(iii)(B) states:

''The director shall notify the public . . . for the duration of the public comment period, on a public website identified by the director.''

(3) Chapter 33.1–15–01.2(q)

* In section 33.1–15–01.2(q), public participation, paragraph (q)(2)(c) is being revised to add the phrase ''draft permit to construct.''

This phrase is approvable, as it strengthens the requirement as to what is to be published during the public comment period.

F. Revisions to Chapter 33.1–15–19 (Visibility Protection)

* In section 33.1–15–19–01.1 and 33.1–15–19–01.2, line 2, the reference to subsection 33.1–15–15–01 is corrected by adding ''.2.''

This revision is approvable, as it is administrative in nature.

G. Revisions to Chapter 33.1–15–20 (Control of Emissions From Oil and Gas Well Production Facilities)

(1) Chapter 33.1–15–20–04.2

* In section 33.1–15–20–04.2, the paragraph is revised to indicate that all flares at a production facility, not just those combusting gas containing hydrogen sulfide, must be maintained and operated in good working order. On the last line, ''sulfur dioxide'' is replaced with ''air contaminants as.''

This revision is approvable, as it expands the amount of flares which must be maintained and operated in good working order.

(2) Section 33.1–15–20–04.3

* In section 33.1–15–20–04.3, the word ''volatile'' is removed to be consistent with Chapter 33.1–15–07, and the words ''gas'' and ''vapor'' are pluralized.

This revision is approvable, as it is administrative in nature.

* In section 33.1–15–20–04.3, the reference to gas containing hydrogen sulfide is removed and replaced with ''at production facility.''

This revision is approvable, as it is administrative in nature.

H. Revisions to Section 2.15 (Respecting Boards)

* North Dakota is also revising section 2.15 (Respecting Boards) located in North Dakota's EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures.

This revision is approvable. Section 128 of the CAA requires SIPs to contain requirements for Boards that approve permits and/or enforcement actions and conflict of interest requirements for state personnel and Boards. North Dakota's initial submittal of these requirements was approved by the EPA on July 20, 2013 (78 FR 45866). When the North Dakota Department of Environmental

Quality (DEQ) transitioned from the North Dakota Department of Public Health, their Conflict of Interest requirements changed. This revision updates section 2.15 of the SIP to match the current DEQ requirements.

III. Proposed Action

For the reasons described in section II of this proposed rulemaking, the EPA is proposing to approve North Dakota's August 3, 2020, submittal revisions to NDAC, Article 33.1–15 (Air Pollution Control) except for revisions to 33.1–15–25 (Regional Haze Requirements) which were addressed in a separate rulemaking. The EPA is also proposing to approve North Dakota's revisions to section 2.15 (Respecting Boards) located in North Dakota's EPA Approved Nonregulatory Provisions and Quasi-Regulatory Measures. Our action is based on an evaluation of North Dakota's revisions against the requirements of CAA section 110(a)(2)(c) and regulatory requirements under 40 CFR 51.160–164 and 40 CFR 51.166.

IV. Incorporation by Reference

In this document, the EPA is proposing to include regulatory text in an EPA final rule that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the revisions described in section II. The EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and at the EPA Region 8 Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, 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, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve 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 Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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 CAA; 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, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Greenhouse gases, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 22, 2021.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

[FR Doc. 2021–16093 Filed 7–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2021–0242; FRL–8725–01–R9]

Air Plan Approval; Nevada, Las Vegas Valley; Second 10-Year Carbon Monoxide Limited Maintenance Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a Nevada State Implementation Plan (SIP) revision submitted by the Nevada Department of Environmental Protection (NDEP). On September 27, 2010, the EPA redesignated the Las Vegas Valley area from nonattainment to attainment for the carbon monoxide (CO) national ambient air quality standard (NAAQS or ''standard'') and approved the State's CO maintenance plan ensuring the area would maintain the NAAQS for ten years through 2020. On June 18, 2019, NDEP submitted to the EPA a second 10-year limited maintenance plan (LMP) for the Las Vegas Valley area for the CO NAAQS. The LMP addresses maintenance of the CO NAAQS for a second 10-year period ending in 2030.

DATES: Any comments must arrive by September 1, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2021–0166 at *https://www.regulations.gov*. For comments submitted at *Regulations.gov*, follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov*. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit

https://www.epa.gov/dockets/commenting-epa-dockets. If you need assistance in a language other than English or if you are a person with disabilities who needs a reasonable accommodation at no cost to you, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Jonathan Szeto, Air Planning Office (AIR–2), EPA Region IX, (415) 947–4278, *szeto.jonathan@epa.gov*.

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us,'' and ''our'' refer to the EPA.

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I. Background

Carbon monoxide is a colorless, odorless gas that is generally emitted from the incomplete combustion of carbon-containing fuels. The largest sources of CO in ambient environments are cars, trucks, and other vehicles and machineries that burn fossil fuels. Inhalation of CO can impair oxygen delivery to vital organs and tissues. Those with pre-existing heart disease or other conditions that make one unable to compensate for tissue hypoxia are particularly vulnerable to the cardiovascular effects of ambient CO, especially during exercise or when under increased stress. At high levels, CO exposure can also lead to dizziness, confusion, and unconsciousness.[1]

In 1971 the EPA established primary and secondary NAAQS for CO at 9 parts per million (ppm), averaged over an 8-hour period, and at 35 ppm, averaged over a 1-hour period.[2] On September 13, 1985, the EPA retained the primary standards without revision and revoked the secondary standards.[3] The EPA retained the primary standards without revision again in both 1994[4] and 2011.[5] The EPA retained the primary standards based on scientific evidence demonstrating that the existing standards are requisite to protect public health with an adequate margin of safety. The EPA also found that analysis of both the non-climate and climate welfare effects of CO are insufficient to provide support for a secondary standard.

Following the enactment of the Clean Air Act (CAA or ''Act'') Amendments of 1990, the EPA designated the Las Vegas Valley area as a ''Moderate'' nonattainment area.[6] The area was reclassified as a ''Serious'' nonattainment area on October 2, 1997, when the EPA determined the area had not attained the standard after receiving a one-year extension of the 1995 attainment date.[7] Under the CAA, states are required to adopt and submit SIPs to attain the NAAQS in nonattainment areas within their state.

Under CAA section 175A, one of the criteria for an area to be redesignated from nonattainment to attainment is the approval of a maintenance plan. The maintenance plan must, among other requirements, ensure control measures are in place such that the area will continue to maintain the standard for the period extending 10 years after redesignation, and include contingency provisions to assure that violations of the NAAQS will be promptly remedied.

In 1994, the EPA set forth new guidelines establishing a streamlined process for certain nonattainment areas to meet CAA section 175A maintenance plan requirements.[8] This process provides for maintenance by demonstrating that future violations of the standard are unlikely to occur because the area's design values[9] are well below the NAAQS, and based on the historical stability of the area's air quality. A design value is considered well below the NAAQS when it is less than or equal to 85 percent of the standard. For CO specifically, this would be 85 percent of the 9 ppm 8-hour CO standard, or 7.65 ppm. The EPA refers to this streamlined demonstration as a limited maintenance plan (LMP). Although the LMP guidelines originally addressed the ozone NAAQS, the EPA extended the provisions to apply to other pollutants and issued guidance specific for CO nonattainment areas.[10] The LMP must be submitted as a SIP revision and should include an attainment emissions inventory, maintenance demonstration, provisions for the continued operation of the ambient air quality monitoring network for verification of continued attainment, a contingency plan in the event of a future violation of the NAAQS, and conformity determination provisions.[11] [12]

In September 2010, the EPA approved the ''Carbon Monoxide Redesignation Request and Maintenance Plan, Las Vegas Valley Nonattainment Area, Clark County, Nevada (September 2008)'' for the Las Vegas Valley area and redesignated the area to attainment.[13] Under CAA section 175A, at the end of the eighth year after the effective date of redesignation, the state must submit a second maintenance plan to ensure ongoing maintenance of the standard for an additional ten years. On June 18, 2019, the State of Nevada submitted the ''Second 10-Year Carbon Monoxide Limited Maintenance Plan: Las Vegas Valley Maintenance Area, Clark County, Nevada (May 2019)'' (''2019 LMP'') for the Las Vegas Valley area to fulfill the second maintenance plan requirement in CAA section 175A.[14] The 2019 LMP includes a demonstration that the area is expected to remain in attainment of the CO NAAQS through the last year of the second 10-year maintenance period, that is, through the remainder of the area's full 20-year maintenance period.

II. Nevada's SIP Submittal

On June 18, 2019, NDEP submitted the 2019 LMP to the EPA as a revision to the Nevada SIP. The submittal includes the LMP and appendices. Appendices to the plan include air quality data, emissions inventory information, air quality monitoring information, and documentation of the public review process.

III. The EPA's Evaluation of Nevada's SIP Submittal

A. Procedural Requirements

Sections 110(a)(2) and 110(l) of the CAA require that a reasonable notice and public hearing occur before revisions to a SIP can be adopted by the state. Specifically, under 40 CFR part 51, subpart F, the EPA requires that

[1] 76 FR 54294 (August 31, 2011).
[2] 36 FR 8186 (April 30, 1971).
[3] 50 FR 37484 (September 13, 1985).
[4] 59 FR 38906 (August 1, 1994).
[5] 75 FR 54194 (August 31, 2011).
[6] 56 FR 56694 (November 6, 1991).
[7] 62 FR 51604 (October 2, 1997).
[8] Memorandum dated November 16, 1994, from Sally L Shaver, Director, Air Quality Strategies & Standards Divisions (MD–15) to Air Branch Directors, Regions I–X, ''Limited Maintenance Plan Option for Nonclassifiable Ozone Nonattainment Areas.''
[9] A design value is a statistic that describes the air quality status of a certain pollutant for a given location relative to its NAAQS.
[10] Memorandum dated October 6, 1995, from Joseph W. Paisie, Group Leader, Air Quality Management Division (MD–15) to Air Branch Chiefs, Regions I–X, ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas'' (''Paisie Memo'').
[11] Id. at 3–5.
[12] Memorandum dated September 4, 1992, from John Calcagni, Director, Air Quality Management Division (MD–15), Regional Air Division Directors, Regions I–X, ''Procedures for Processing Requests to Redesignate Areas to Attainment.''
[13] 75 FR 59090 (September 27, 2010).
[14] Letter of submittal dated June 13, 2019, from Greg Lovato, Administrator, Nevada Division of Environmental Protection, to Elizabeth Adams, Air Division Director, U.S. Environmental Protection Agency Region IX (submitted electronically June 18, 2019).

there must be a publication of a notice by prominent advertisement in the relevant geographic area of the proposed SIP revision, a public comment period of at least 30 days, and an opportunity for a public hearing.

The Clark County Department of Environment and Sustainability (CCDES) [15] published a notice of a 30-day comment period and notice of a public hearing for the 2019 LMP on the Clark County website, and the department's website, Twitter, and Facebook pages. An email notice was distributed to officials in relevant cities as well as in state and local-level departments, districts, authorities, commissions, and associations. The CCDES held a public comment period from February 15, 2019 to March 18, 2019. No formal comments were submitted. On May 7, 2019, the Clark County Board of County Commissioners held a public hearing on the 2019 LMP. No formal comments were submitted during this hearing. The CCDES then forwarded the 2019 LMP to the State of Nevada and the State submitted the plan to the EPA as a revision to the Nevada SIP. The process followed by the CCDES adheres with procedural requirements for SIP revisions outlined under CAA section 110 and the EPA's implementing regulations.

B. LMP Requirements

The EPA reviewed the 2019 LMP that addresses maintenance of the CO NAAQS within the Las Vegas Valley area through the end of the 20-year period following the area's redesignation, as required under CAA section 175A(b).

1. Attainment Emissions Inventory

For maintenance plans, a state should develop a comprehensive, accurate inventory of actual emissions for an attainment year to identify the level of emissions sufficient to maintain the NAAQS. For CO, the inventory should represent the typical winter day emissions of CO for the time period associated with the monitoring data showing attainment.[16] The 2019 LMP includes a CO attainment inventory for the Las Vegas Valley area that reflects typical winter weekday emissions in 2017. Table 1 presents a summary of the inventory for the year contained in the maintenance plan. Under an LMP, states are not required to project emissions over the maintenance period.

TABLE 1—2017 AVERAGE WINTER WEEKDAY CO EMISSIONS FOR THE LAS VEGAS VALLEY AREA

[Tons per day]

Point	0.93
Nonpoint	43.48
Aviation	12.53
Onroad Mobile	217.18
Nonroad Mobile	114.35
Total	448.96

CCDES derived point source emissions using semiannual compliance reports submitted to the agency by stationary sources located in the Las Vegas Valley area. These reports are required by CCDES' federally-approved CAA title V operating permits program and include monthly reporting data for the facility.[17] CCDES derived the nonpoint source emissions from the EPA's 2016 modeling platform (alpha version) and used 2016 as a surrogate for 2017 because the 2017 National Emissions Inventory (NEI) for nonpoint sources was not available at the time CCDES developed the 2019 LMP. CCDES determined that the differences between 2016 and 2017 would be insignificant. Aviation operation data for 2014 and 2017 were obtained from the Federal Aviation Administration's air traffic activity system and terminal area forecast databases and used in conjunction with the 2014 NEI to estimate aviation CO emissions for 2017. Onroad and nonroad mobile source data were generated using the latest release of the EPA's Motor Vehicle Emission Simulator (MOVES) model version MOVES2014b.

Based on our review of the methods, models, and assumptions used by CCDES to develop the CO estimates, we find that the 2019 LMP for the Las Vegas Valley CO maintenance area includes a comprehensive, accurate inventory of CO emissions in the year 2017, and conclude that the plan's inventories are acceptable for the purposes of a subsequent maintenance plan under CAA section 175A(b).

2. Maintenance Demonstration

Consistent with prior EPA guidance, if a maintenance area demonstrates a maximum 8-hour CO design value of less than or equal to 85 percent of the CO NAAQS, or 7.65 ppm, for eight consecutive quarters, then the EPA considers the area to have met the maintenance plan demonstration requirement and that the area will maintain the NAAQS for the second 10-year maintenance period.[18] Such a demonstration also assumes continued applicability of prevention of significant deterioration (PSD) requirements,[19] continued implementation of any existing control measures in the SIP, and that federal measures will remain in place through the end of the second 10-year maintenance period. The EPA does not require areas using the LMP option to project emissions over the maintenance period.

Table 2 presents the design values for the Las Vegas Valley area over the 2012–2020 period. As shown in Table 2, historically, the area has consistently been well below 85 percent of the NAAQS. Because the CO design values in the Las Vegas Valley area are below the LMP threshold over the most recent eight quarters, the EPA finds that the State has adequately demonstrated that the area will continue to maintain the CO NAAQS over the second 10-year maintenance period and in the future.

TABLE 2—CURRENT AND HISTORICAL CO DESIGN VALUES (DV) FOR THE LAS VEGAS VALLEY AREA

Year	Highest second maximum 8-hour CO value (ppm)				DV (ppm)	Is DV less than 7.65 ppm?
	Jerome Mack (320030540)	J.D. Smith (320032002)	Rancho & Teddy (320031501)	Sunrise Acres (320030540)		
2012	2.8	2.1	.....	3.1	3.1	Yes.
2013	2.8	2.4	.....	3.1	3.1	Yes.

[15] Formerly Clark County Department of Air Quality.

[16] Paisie Memo, 3.

[17] CCDES used reporting data for the CO season months January, February, and December 2017 to develop emissions for those months and convert to daily emissions. See 2019 LMP, 18.

[18] Paisie Memo, 3.

[19] PSD applies to new major sources or major modifications at existing sources for pollutants where the area of the source's location is designated by the EPA as attainment or unclassifiable with the NAAQS. Its requirements include, but are not limited to, the following: Installation of best available control technology, an air quality analysis, an additional impact analysis, and public involvement.

TABLE 2—CURRENT AND HISTORICAL CO DESIGN VALUES (DV) FOR THE LAS VEGAS VALLEY AREA—Continued

Year	Highest second maximum 8-hour CO value (ppm)				DV (ppm)	Is DV less than 7.65 ppm?
	Jerome Mack (320030540)	J.D. Smith (320032002)	Rancho & Teddy (320031501)	Sunrise Acres (320030540)		
2014	2.7	2.4	.....	2.9	2.9	Yes.
2015	2.7	2.2	.....	2.8	2.8	Yes.
2016	2.3	2	.....	2.6	2.6	Yes.
2017	2.35	2	[c] 1.5	2.8	2.8	Yes.
2018	2.5	[b] 1.9	1.5	2.8	2.8	Yes.
2019	2.3	.....	1.4	2.8	2.8	Yes.
2020 [a]	2.1	.....	1.4	2.4	2.4	Yes.

Source: EPA, Air Quality System, Design Value Report, March 16, 2021.
[a] CO design values have no annual completeness requirement.
[b] The J.D. Smith station was permanently shut down with the EPA's approval on December 31, 2017, due to measurement challenges posed by siting obstructions.
[c] The Rancho & Teddy station opened in 2015 and began monitoring CO in January 2017.

3. Monitoring Network and Verification of Continued Attainment

The EPA periodically reviews the CO monitoring network operated and maintained by CCDES in accordance with 40 CFR part 58. This network is consistent with the Clark County ambient air monitoring network plan (AMNP) submitted annually to the EPA after a public notification and comment process. The EPA has reviewed and approved the AMNP every year for the past three years from 2018–2020. The EPA is also required to conduct technical systems audits (TSA) every three years to ensure quality assurance of monitoring organizations.[20] The most recent TSA for CCDES was in 2018, and the EPA found that CCDES's air monitoring program meets EPA's requirements.[21]

To verify the attainment status of the area over the maintenance period, the maintenance plan should contain provisions for continued operations of an EPA-approved monitoring network in accordance with 40 CFR part 58. The CCDES's network in the Las Vegas Valley area has been approved by the EPA in accordance with 40 CFR part 58.[22] Furthermore, the CCDES has committed to continue to operate an air quality monitoring network in the Las Vegas Valley area in accordance with the EPA requirements to verify continued attainment of the CO NAAQS.[23] For the reasons stated in this section of the notice, we find Clark County's monitoring network adequate to verify continued attainment of the CO NAAQS in the Las Vegas Valley area.

4. Contingency Plan

Section 175A(d) of the CAA requires that a maintenance plan include contingency provisions. The purpose of these provisions is to prevent future violations of the NAAQS or promptly remediate any NAAQS violations that might occur during the maintenance period. These contingency provisions need not be fully adopted regulations at the time of the redesignation. However, the contingency plan is an enforceable part of the SIP and should ensure that contingency measures are adopted quickly once the contingency plan is triggered. The contingency plan should also identify the measures to be expeditiously adopted and provide a schedule and procedure for adoption and implementation. The state is also required to identify triggers that will be used to determine when contingency measures will need to be implemented.

In the 2019 LMP, the CCDES retains the reduced Reid vapor pressure (RVP) gasoline program contingency measure from its first CO maintenance plan as a contingency measure. The RVP gasoline program relaxed the RVP from wintertime fuels sold in Clark County from 9.0 pounds per square inch (psi) to 13.5 psi, thereby increasing fuel volatility and therefore fuel-related emissions. The EPA approved this measure, finding that relaxation of RVP would not interfere with maintenance of the CO standard in the area.[24] The RVP gasoline program contingency measure would reinstate the prior, lower RVP level. That is, if future CO levels trigger contingency measures, the CCDES will seek reinstatement and tightening of the RVP standard back to 9.0 psi. This contingency measure would be triggered by a verified second exceedance over 9 ppm during the winter season (October 1 through March 31) within a consecutive two-year period.

The EPA proposes to find that the contingency provisions in the 2019 LMP satisfy the contingency measure requirements of CAA section 175A for the second 10-year maintenance plan period.

IV. Transportation Conformity

Transportation conformity is required by section 176(c) of the CAA. Conformity to a SIP means that transportation activities will not produce new air quality violations, worsen existing violations, or delay timely attainment of the NAAQS. The EPA's conformity rule at 40 CFR part 93 requires that transportation plans, programs, and projects conform to SIPs and establishes the criteria and procedures for determining conformity. The conformity rule generally requires a demonstration that emissions from the regional transportation plan (RTP) and the transportation improvement plan (TIP) are consistent with the motor vehicle emissions budget (MVEB or ''budget'') contained in the control strategy SIP revision or maintenance plan.[25] A budget is defined as the level of mobile source emissions of a pollutant relied upon in the attainment or maintenance demonstration to attain or maintain compliance with the

[20] 40 CFR 58 Appendix A, section 2.5.

[21] Letter dated August 23, 2018 from Elizabeth J. Adams, Acting Director, Air Division Region IX, to Marci Henson, Director, Clark County Department of Air Quality with attached ''Technical Systems Audit of the Ambient Air Monitoring Program: Clark County Department of Air Quality October 23–25, 2017 and January 16–18, 2018.''

[22] For further details, see CCDES's 2020 Annual Monitoring Network Plan (AMNP), the EPA's approval letter for the 2020, 2019 and 2018 AMNP, as well as the EPA's Clark County 2018 TSA report, in the docket for this action.

[23] See 2019 LMP, Section 3.3, ''Monitoring Network/Verification of Continued Attainment,'' 21.

[24] 75 FR 59090.

[25] See 40 CFR 93.101, 93.118, and 93.124.

NAAQS in the nonattainment or maintenance area.[26]

Under the conformity rule, areas submitting an LMP for the second 10-year maintenance plan may demonstrate conformity without a regional emissions analysis as outlined in 40 CFR 93.109(e). When the EPA approves an LMP, the EPA is concluding that a budget may be treated as essentially not constraining for the length of the maintenance period. Areas that qualify for an LMP may demonstrate conformity without a regional emissions analysis because it is unreasonable to expect that such an area will experience so much growth in the 10-year period of the LMP that a violation of the CO NAAQS would result.[27] All actions that would require transportation conformity determinations for the Las Vegas Valley area under the transportation conformity rule provisions would be considered to have already satisfied the regional emissions analysis and ''budget test'' requirements in 40 CFR 93.118 as a result of our final approval of the 2019 LMP.

However, because LMP areas are still maintenance areas, approval of the 2019 LMP would not relieve transportation agencies of certain determinations still required for transportation plans, programs, and projects. Specifically, RTPs, TIPs and transportation projects must still demonstrate that they are fiscally constrained,[28] meet the criteria for consultation,[29] and provide for timely implementation of transportation control measures from the applicable implementation plan.[30] Conformity determinations for RTPs and TIPs must also be determined no less frequently than every four years, and conformity of plan and TIP amendments and transportation projects demonstrated in accordance with the timing requirements specified in 40 CFR 93.104. For projects to be approved they must be listed in a currently conforming RTP and TIP.[31] In addition, projects in LMP areas are required to meet the applicable criteria for CO hot spot analyses to satisfy ''project level'' conformity determinations,[32] which must also incorporate the latest planning assumptions and models available.[33]

If the area should monitor CO concentrations at or above the limited maintenance eligibility criteria, or 7.65 ppm, then that maintenance area would no longer qualify for a LMP and would revert to a full maintenance plan. In this event, the LMP would remain applicable for conformity purposes only until the full maintenance plan is submitted and the EPA has either found its motor vehicle emissions budget adequate for conformity purposes or approves the full maintenance plan SIP revision. At that time regional emissions analyses would resume as a transportation conformity criterion.

The EPA posted Las Vegas Valley's 2019 LMP for CO on its adequacy review website on June 23, 2021.[34] The EPA will accept comments from the public for up to 30 days after the LMP has been posted on the website. The EPA will consider the comments and then may elect to proceed with finding the 2019 LMP adequate for transportation conformity purposes either as part of the SIP's final approval or in a separate notice of adequacy. The EPA's adequacy review process is described in 40 CFR part 93.118(f).

If finalized, our approval of the 2019 LMP would effectively affirm our adequacy finding such that no regional emissions analysis for future transportation CO conformity determinations are required for the 2019 LMP period and beyond. The other transportation conformity requirements listed above would continue to apply.

In addition to transportation conformity, approval of the 2019 LMP would have implications for general conformity.[35] Federal actions subject to general conformity would be presumed to conform under a limited maintenance plan as actions in this area will automatically satisfy the budget test of 40 CFR 93.158(a)(5)(i)(A), as described in in an EPA memorandum entitled ''Limited Maintenance Plan Option for Nonclassifiable CO Nonattainment Areas'' on limited maintenance plans for CO nonattainment areas.[36]

V. Proposed Action and Public Comment

Under section 110(k)(3) of the CAA, the EPA is proposing to approve the 2019 LMP as a revision to the Nevada SIP because we find that it satisfies the requirements of section 175A of the CAA.

The 2019 LMP adequately demonstrates maintenance of the CONAAQS well below the standard through documentation of monitoring data showing the historical CO design values of the area. It also satisfies the other core provisions of an LMP: It has an accurate and comprehensive emissions inventory representing attainment, a contingency plan, and a commitment to continue operation of an acceptable ambient monitoring network to verify continued attainment over the second 10-year period. We find the 2019 LMP to be sufficient to provide for maintenance of the CO NAAQS in the Las Vegas Valley area over the second 10-year maintenance period (through 2030) and thereby satisfy the requirements for such a plan under CAA section 175A(b).

The EPA is soliciting public comments on the issues discussed in this notice. We will accept comments from the public on this proposal for the next 30 days and will consider these comments before taking final action.

VI. 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, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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

[26] Further information concerning the EPA's interpretations regarding MVEBs can be found in the preamble to the EPA's November 24, 1993, transportation conformity rule. See 58 FR 62193–62196, November 24, 1993.

[27] Paisie Memo, 3–4.

[28] 40 CFR 93.108.

[29] 40 CFR 93.105 and 40 CFR 93.112.

[30] 40 CFR 93.113.

[31] 40 CFR 93.114 and 93.115.

[32] 40 CFR 93.116 and 40 CFR 93.123.

[33] 40 CFR 93.110 and 40 CFR 93.111, respectively. See 40 CFR 93.109(b), Table 1.

[34] *https://www.epa.gov/state-and-local-transportation/adequacy-review-state-implementation-plan-sip-submissions-conformity.*

[35] 40 CFR part 93 Subpart B.

[36] Paisie Memo, 4–5.

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 the EPA with the discretionary authority to address disproportionate human health or environmental effects with practical, appropriate, and legally permissible methods under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the 2019 LMP is not proposed to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. The Las Vegas Tribe of Paiute Indians has areas of Indian country located in the Las Vegas Valley CO maintenance area. In those areas of Indian country, the 2019 LMP does not apply, and therefore, this proposed action does not have tribal implications and would not, if approved, impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Carbon Monoxide, Pollution.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: July 22, 2021.

Deborah Jordan,

Acting Regional Administrator, Region IX.

[FR Doc. 2021–16453 Filed 7–30–21; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2021–0217; FRL–8690–01–R3]

Approval and Promulgation of Air Quality Plans; Pennsylvania; Reasonably Available Control Technology (RACT) Determinations for Case-by-Case Sources Under the 1997 and 2008 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve multiple state implementation plan (SIP) revisions submitted by the Commonwealth of Pennsylvania. These revisions were submitted by the Pennsylvania Department of Environmental Protection (PADEP) to establish and require reasonably available control technology (RACT) for fourteen major sources of volatile organic compounds (VOC) and/or nitrogen oxides (NO_X) pursuant to the Commonwealth of Pennsylvania's conditionally approved RACT regulations. In this rulemaking action, EPA is proposing to approve source-specific (also referred to as ''case-by-case'') RACT determinations for sources at fourteen major sources submitted by PADEP. These RACT evaluations were submitted to meet RACT requirements for the 1997 and 2008 8-hour ozone national ambient air quality standards (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 1, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2021–0217 at *https://www.regulations.gov,* or via email to *opila.marycate@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Ms. Gwendolyn Supplee, Permits Branch (3AD10), Air and Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2763. Ms. Supplee can also be reached via electronic mail at *supplee.gwendolyn@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 7, 2020, PADEP submitted a revision to its SIP to address case-by-case NO_X and/or VOC RACT for sources at fourteen major facilities. This SIP revision is intended to address the NO_X and/or VOC RACT requirements under sections 182 and 184 of the CAA for the 1997 and 2008 8-hour ozone NAAQS. Table 1 of this document lists the SIP submittal date and the facilities included in PADEP's submittal. Although submitted in one SIP revision by PADEP, EPA views each facility as a separable SIP revision and may take separate final action on one or more facilities.

For additional background information on Pennsylvania's ''presumptive'' RACT II SIP see 84 FR 20274 (May 9, 2019) and on Pennsylvania's source-specific or ''case-by-case'' RACT determinations see the appropriate technical support document (TSD) which is available online at *https://www.regulations.gov,* Docket No. EPA–R03–OAR–2021–0217.

TABLE 1—PADEP SIP SUBMITTALS FOR MAJOR NO_X AND/OR VOC SOURCES IN PENNSYLVANIA SUBJECT TO SOURCE-SPECIFIC RACT UNDER THE 1997 AND 2008 8-HOUR OZONE STANDARD

SIP submittal date	Major source (county)
5/7/2020	Dart Container Corporation of Pennsylvania—East Lampeter (Lancaster). Dart Container Corporation of Pennsylvania—Leola (Lancaster). Carpenter Latrobe Specialty Metals, LLC (Westmoreland). ATI Flat Rolled Products Holdings, LLC (Westmoreland). CONSOL Pennsylvania Coal Company, LLC (Greene). IPSCO Koppel Tubular Corporation—IPSCO Ambridge (Beaver). IPSCO Koppel Tubular Corporation—IPSCO Koppel (Beaver). MarkWest Liberty Bluestone Plant (Butler). York Group, Inc. York Casket Manufacturing (York). Omnova Solutions Inc—Jeannette Plant (Westmoreland). Jessop Steel LLC—Washington Plant (Washington). Kawneer Commercial Windows LLC (Butler). Tennessee Gas Pipeline Co., LLC, Marienville STA 307 (Forest). Mack Truck—Macungie (Lehigh).

I. Background

A. 1997 and 2008 8-Hour Ozone NAAQS

Ground level ozone is not emitted directly into the air but is created by chemical reactions between NO_X and VOC in the presence of sunlight. Emissions from industrial facilities, electric utilities, motor vehicle exhaust, gasoline vapors, and chemical solvents are some of the major sources of NO_X and VOC. Breathing ozone can trigger a variety of health problems, particularly for children, the elderly, and people of all ages who have lung diseases such as asthma. Ground level ozone can also have harmful effects on sensitive vegetation and ecosystems.

On July 18, 1997, EPA promulgated a standard for ground level ozone based on 8-hour average concentrations. 62 FR 38856. The 8-hour averaging period replaced the previous 1-hour averaging period, and the level of the NAAQS was changed from 0.12 parts per million (ppm) to 0.08 ppm. EPA has designated two moderate nonattainment areas in Pennsylvania under the 1997 8-hour ozone NAAQS, namely Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE (the Philadelphia Area) and Pittsburgh-Beaver Valley (the Pittsburgh Area). See 40 CFR 81.339.

On March 12, 2008, EPA strengthened the 8-hour ozone standards, by revising its level to 0.075 ppm averaged over an 8-hour period (2008 8-hour ozone NAAQS). On May 21, 2012, EPA designated five marginal nonattainment areas in Pennsylvania for the 2008 8-hour ozone NAAQS: Allentown-Bethlehem-Easton, Lancaster, Reading, the Philadelphia Area, and the Pittsburgh Area. 77 FR 30088; see also 40 CFR 81.339.

On March 6, 2015, EPA announced its revocation of the 1997 8-hour ozone NAAQS for all purposes and for all areas in the country, effective on April 6, 2015. 80 FR 12264. EPA has determined that certain nonattainment planning requirements continue to be in effect under the revoked standard for nonattainment areas under the 1997 8-hour ozone NAAQS, including RACT.

B. RACT Requirements for Ozone

The CAA regulates emissions of NO_X and VOC to prevent photochemical reactions that result in ozone formation. RACT is an important strategy for reducing NO_X and VOC emissions from major stationary sources within areas not meeting the ozone NAAQS.

Areas designated nonattainment for the ozone NAAQS are subject to the general nonattainment planning requirements of CAA section 172. Section 172(c)(1) of the CAA provides that SIPs for nonattainment areas must include reasonably available control measures (RACM) for demonstrating attainment of all NAAQS, including emissions reductions from existing sources through the adoption of RACT. Further, section 182(b)(2) of the CAA sets forth additional RACT requirements for ozone nonattainment areas classified as moderate or higher. Section 182(b)(2) of the CAA sets forth requirements regarding RACT for the ozone NAAQS for VOC sources. Section 182(f) subjects major stationary sources of NO_X to the same RACT requirements applicable to major stationary sources of VOC.[1]

Section 184(b)(1)(B) of the CAA applies the RACT requirements in section 182(b)(2) to nonattainment areas classified as marginal and to attainment areas located within ozone transport regions established pursuant to section 184 of the CAA. Section 184(a) of the CAA established by law the current Ozone Transport Region (OTR) comprised of 12 eastern states, including Pennsylvania. This requirement is referred to as OTR RACT. As noted previously, a ''major source'' is defined based on the source's potential to emit (PTE) of NO_X, VOC, or both pollutants, and the applicable thresholds differ based on the classification of the nonattainment area in which the source is located. See sections 182(c)–(f) and 302 of the CAA.

Since the 1970's, EPA has consistently defined ''RACT'' as the lowest emission limit that a particular source is capable of meeting by the application of the control technology that is reasonably available considering technological and economic feasibility.[2]

EPA has provided more substantive RACT requirements through implementation rules for each ozone NAAQS as well as through guidance. In 2004 and 2005, EPA promulgated an implementation rule for the 1997 8-hour ozone NAAQS in two phases (''Phase 1 of the 1997 Ozone Implementation Rule'' and ''Phase 2 of the 1997 Ozone Implementation Rule''). 69 FR 23951 (April 30, 2004) and 70 FR 71612 (November 29, 2005), respectively. Particularly, the Phase 2 Ozone Implementation Rule addressed RACT

[1] A ''major source'' is defined based on the source's potential to emit (PTE) of NO_X or VOC, and the applicable thresholds for RACT differs based on the classification of the nonattainment area in which the source is located. See sections 182(c)–(f) and 302 of the CAA.

[2] See December 9, 1976 memorandum from Roger Strelow, Assistant Administrator for Air and Waste Management, to Regional Administrators, ''Guidance for Determining Acceptability of SIP Regulations in Non-Attainment Areas,'' and also 44 FR 53762 (September 17, 1979).

statutory requirements under the 1997 8-hour ozone NAAQS. See 70 FR 71652 (November 29, 2005).

On March 6, 2015, EPA issued its final rule for implementing the 2008 8-hour ozone NAAQS (''the 2008 Ozone SIP Requirements Rule''). 80 FR 12264. At the same time, EPA revoked the 1997 8-hour ozone NAAQS, effective on April 6, 2015.[3] The 2008 Ozone SIP Requirements Rule provided comprehensive requirements to transition from the revoked 1997 8-hour ozone NAAQS to the 2008 8-hour ozone NAAQS, as codified in 40 CFR part 51, subpart AA, following revocation. Consistent with previous policy, EPA determined that areas designated nonattainment for both the 1997 and 2008 8-hour ozone NAAQS at the time of revocation, must retain implementation of certain nonattainment area requirements (*i.e.,* anti-backsliding requirements) for the 1997 8-hour ozone NAAQS as specified under section 182 of the CAA, including RACT. See 40 CFR 51.1100(o). An area remains subject to the anti-backsliding requirements for a revoked NAAQS until EPA approves a redesignation to attainment for the area for the 2008 8-hour ozone NAAQS. There are no effects on applicable requirements for areas within the OTR, as a result of the revocation of the 1997 8-hour ozone NAAQS. Thus, Pennsylvania, as a state within the OTR, remains subject to RACT requirements for both the 1997 8-hour ozone NAAQS and the 2008 8-hour ozone NAAQS.

In addressing RACT, the 2008 Ozone SIP Requirements Rule is consistent with existing policy and Phase 2 of the 1997 Ozone Implementation Rule. In the 2008 Ozone SIP Requirements Rule, EPA requires RACT measures to be implemented by January 1, 2017 for areas classified as moderate nonattainment or above and all areas of the OTR. EPA also provided in the 2008 Ozone SIP Requirements Rule that RACT SIPs must contain adopted RACT regulations, certifications where appropriate that existing provisions are RACT, and/or negative declarations stating that there are no sources in the nonattainment area covered by a specific control technique guidelines (CTG) source category. In the preamble to the 2008 Ozone SIP Requirements Rule, EPA clarified that states must provide notice and opportunity for public comment on their RACT SIP submissions, even when submitting a certification that the existing provisions remain RACT or a negative declaration. States must submit appropriate supporting information for their RACT submissions, in accordance with the Phase 2 of the 1997 Ozone Implementation Rule. Adequate documentation must support that states have considered control technology that is economically and technologically feasible in determining RACT, based on information that is current as of the time of development of the RACT SIP.

In addition, in the 2008 Ozone SIP Requirements Rule, EPA clarified that states can use weighted average NO_X emissions rates from sources in the nonattainment area for meeting the major NO_X RACT requirement under the CAA, as consistent with existing policy.[4] EPA also recognized that states may conclude in some cases that sources already addressed by RACT determinations for the 1979 1-hour and/or 1997 8-hour ozone NAAQS may not need to implement additional controls to meet the 2008 8-hour ozone NAAQS RACT requirement. See 80 FR 12278–12279 (March 6, 2015).

C. Applicability of RACT Requirements in Pennsylvania

As indicated earlier, RACT requirements apply to any ozone nonattainment areas classified as moderate or higher (serious, severe or extreme) under CAA sections 182(b)(2) and 182(f). Pennsylvania has outstanding ozone RACT requirements for both the 1997 and 2008 8-hour ozone NAAQS. The entire Commonwealth of Pennsylvania is part of the OTR established under section 184 of the CAA and thus is subject statewide to the RACT requirements of CAA sections 182(b)(2) and 182(f), pursuant to section 184(b).

At the time of revocation of the 1997 8-hour ozone NAAQS (effective April 6, 2015), only two moderate nonattainment areas remained in the Commonwealth of Pennsylvania for this standard, the Philadelphia and the Pittsburgh Areas. As required under EPA's anti-backsliding provisions, these two moderate nonattainment areas continue to be subject to RACT under the 1997 8-hour ozone NAAQS. Given its location in the OTR, the remainder of the Commonwealth is also treated as moderate nonattainment area under the 1997 8-hour ozone NAAQS for any planning requirements under the revoked standard, including RACT. The OTR RACT requirement is also in effect under the 2008 8-hour ozone NAAQS throughout the Commonwealth, since EPA did not designate any nonattainment areas above marginal for this standard in Pennsylvania. Thus, in practice, the same RACT requirements continue to be applicable in Pennsylvania for both the 1997 and 2008 8-hour ozone NAAQS. RACT must be evaluated and satisfied as separate requirements under each applicable standard.

RACT applies to major sources of NO_X and VOC under each ozone NAAQS or any VOC sources subject to CTG RACT. Which NO_X and VOC sources in Pennsylvania are considered ''major'' and are therefore subject to RACT is dependent on the location of each source within the Commonwealth. Sources located in nonattainment areas would be subject to the ''major source'' definitions established under the CAA. In the case of Pennsylvania, sources located in any areas outside of moderate or above nonattainment areas, as part of the OTR, shall be treated as if these areas were moderate.

In Pennsylvania, the SIP program is implemented primarily by the PADEP, but also by local air agencies in Philadelphia County (the City of Philadelphia's Air Management Services [AMS]) and Allegheny County, (the Allegheny County Health Department [ACHD]). These agencies have implemented numerous RACT regulations and source-specific measures in Pennsylvania to meet the applicable ozone RACT requirements. Historically, statewide RACT controls have been promulgated by PADEP in Pennsylvania Code Title 25—Environmental Resources, Part I—Department of Environmental Protection, Subpart C—Protection of Natural Resources, Article III—Air Resources, (25 Pa. Code) Chapter 129. AMS and ACHD have incorporated by reference Pennsylvania regulations, but have also promulgated regulations adopting RACT controls for their own jurisdictions. In addition, AMS and

[3] On February 16, 2018, the United States Court of Appeals for the District of Columbia Circuit (D.C. Cir. Court) issued an opinion on the 2008 Ozone SIP Requirements Rule. *South Coast Air Quality Mgmt. Dist.* v. *EPA*, No. 15–1115 (D.C. Cir. February 16, 2018). The D.C. Cir. Court found certain parts reasonable and denied the petition for appeal on those. In particular, the D.C. Cir. Court upheld the use of NO_X averaging to meet RACT requirements for 2008 8-hour ozone NAAQS. However, the Court also found certain other provisions unreasonable. The D.C. Cir. Court vacated the provisions it found unreasonable.

[4] EPA's NO_X RACT guidance ''Nitrogen Oxides Supplement to the General Preamble'' (57 FR 55620; November 25, 1992) encouraged states to develop RACT programs that are based on ''area wide average emission rates.'' Additional guidance on area-wide RACT provisions is provided by EPA's January 2001 economic incentive program guidance titled ''Improving Air Quality with Economic Incentive Programs,'' available at *http://www.epa.gov/ttn/oarpg/t1/memoranda/eipfin.pdf.* In addition, as mentioned previously, the D.C. Cir. Court upheld the use of NO_X averaging to meet RACT requirements for 2008 8-hour ozone NAAQS. *South Coast Air Quality Mgmt. Dist.* v. *EPA*, No. 15–1115 (D.C. Cir. February 16, 2018).

ACHD have submitted, through PADEP, separate source-specific RACT determinations as SIP revisions for sources within their respective jurisdictions, which have been approved by EPA. See 40 CFR 52.2020(d)(1).

States were required to make RACT SIP submissions for the 1997 8-hour ozone NAAQS by September 15, 2006. PADEP submitted a SIP revision on September 25, 2006, certifying that a number of previously approved VOC RACT rules continued to satisfy RACT under the 1997 8-hour ozone NAAQS for the remainder of Pennsylvania.[5] PADEP has met its obligations under the 1997 8-hour ozone NAAQS for its CTG and non-CTG VOC sources. See 82 FR 31464 (July 7, 2017). RACT control measures addressing all applicable CAA RACT requirements under the 1997 8-hour ozone NAAQS have been implemented and fully approved in the jurisdictions of ACHD and AMS. See 78 FR 34584 (June 10, 2013) and 81 FR 69687 (October 7, 2016). For the 2008 8-hour ozone NAAQS, states were required to submit RACT SIP revisions by July 20, 2014. On May 16, 2016, PADEP submitted a SIP revision addressing RACT under both the 1997 and 2008 8-hour ozone NAAQS in Pennsylvania. Specifically, the May 16, 2016 SIP submittal intended to satisfy sections 182(b)(2)(C), 182(f), and 184 of the CAA for both the 1997 and 2008 8-hour ozone NAAQS for Pennsylvania's major NO_X and VOC non-CTG sources, except ethylene production plants, surface active agents manufacturing, and mobile equipment repair and refinishing.[6]

D. EPA's Conditional Approval for Pennsylvania's RACT Requirements Under the 1997 and 2008 8-Hour Ozone NAAQS

On May 16, 2016, PADEP submitted a SIP revision addressing RACT under both the 1997 and 2008 8-hour ozone NAAQS in Pennsylvania. PADEP's May 16, 2016 SIP revision intended to address certain outstanding non-CTG VOC RACT, VOC CTG RACT, and major NO_X RACT requirements under the CAA for both standards. The SIP revision requested approval of Pennsylvania's 25 Pa. Code 129.96–100, *Additional RACT Requirements for Major Sources of NO_X and VOCs* (the ''presumptive'' RACT II rule). Prior to the adoption of the RACT II rule, Pennsylvania relied on the NO_X and VOC control measures in 25 Pa. Code 129.92–95, *Stationary Sources of NO_X and VOCs,* (the RACT I rule) to meet RACT for non-CTG major VOC sources and major NO_X sources. The requirements of the RACT I rule remain in effect and continue to be implemented as RACT.[7] On September 26, 2017, PADEP submitted a supplemental SIP revision which committed to address various deficiencies identified by EPA in their May 16, 2016 ''presumptive'' RACT II rule SIP revision.

On May 9, 2019, EPA conditionally approved the RACT II rule based on PADEP's September 26, 2017 commitment letter.[8] See 84 FR 20274. In EPA's final conditional approval, EPA noted that PADEP would be required to submit, for EPA's approval, SIP revisions to address any facility-wide or system-wide averaging plan approved under 25 Pa. Code 129.98 and any case-by-case RACT determinations under 25 Pa. Code 129.99. PADEP committed to submitting these additional SIP revisions within 12 months of EPA's final conditional approval, specifically May 9, 2020.

Therefore, as authorized in CAA section 110(k)(3) and (k)(4), Pennsylvania was required to submit the following as case-by-case SIP revisions, by May 9, 2020, for EPA's approval as a condition of approval of 25 Pa. Code 128 and 129 in the May 16, 2016 SIP revision: (1) All facility-wide or system-wide averaging plans approved by PADEP under 25 Pa. Code 129.98 including, but not limited to, any terms and conditions that ensure the enforceability of the averaging plan as a practical matter (*i.e.,* any monitoring, reporting, recordkeeping, or testing requirements); and (2) all source-specific RACT determinations approved by PADEP under 25 Pa. Code 129.99, including any alternative compliance schedules approved under 25 Pa. Code 129.97(k) and 129.99(i); the case-by-case RACT determinations submitted to EPA for approval into the SIP should include any terms and conditions that ensure the enforceability of the case-by-case or source-specific RACT emission limitation as a practical matter (*i.e.,* any monitoring, reporting, recordkeeping, or testing requirements). See May 9, 2019 (84 FR 20274). Through multiple submissions between 2017 and 2020, PADEP has submitted to EPA for approval various SIP submissions to implement its RACT II case-by-case determinations and averaging plans. This proposed rulemaking is based on EPA's review of one of these SIP revisions.

II. Summary of SIP Revisions

In order to satisfy a requirement from EPA's May 9, 2019 conditional approval, PADEP has submitted to EPA, SIP revisions addressing case-by-case RACT requirements for major sources in Pennsylvania subject to 25 Pa. Code 129.99. As noted in Table 1 of this document, on May 7, 2020, PADEP submitted to EPA, a SIP revision pertaining to Pennsylvania's case-by-case NO_X and/or VOC RACT determinations for sources located at numerous major NO_X and VOC emitting facilities located in the Commonwealth. PADEP provided documentation in its SIP revisions to support its case-by-case RACT determinations for affected emission units at each major NO_X and VOC emitting facilities subject to 25 Pa. Code 129.99.

In the Pennsylvania RACT SIP revision, PADEP included a case-by-case RACT determination for the existing emissions units at each of these major sources of NO_X and/or VOC that required a source specific RACT determination. In PADEP's RACT determinations an evaluation was completed to determine if previously SIP-approved, case-by-case RACT requirements (herein referred to as RACT I) were more stringent and required to be retained in the sources Title V air quality permit and subsequently, the Federally-approved SIP, or if the new case-by-case RACT requirements are more stringent and supersede the previous Federally-approved provisions.

EPA, in this action, is taking action on sources at fourteen major NO_X and/or VOC emitting facilities in Pennsylvania, subject to Pennsylvania's case-by-case RACT requirements, as summarized in Table 2.

[5] The September 15, 2006 SIP submittal initially included Pennsylvania's certification of NO_X RACT regulations; however, NO_X RACT portions were withdrawn by PADEP on June 27, 2016.

[6] EPA's conditional approval of PADEP's May 16, 2016 SIP revision covered relevant sources located in both Philadelphia and Allegheny County, Pennsylvania.

[7] These requirements were initially approved as RACT for Pennsylvania under the 1979 1-hour ozone NAAQS.

[8] On August 27, 2020, the Third Circuit Court of Appeals vacated three provisions of Pennsylvania's presumptive RACT II rule applicable to certain coal-fired power plants. *Sierra Club* v. *EPA,* No. 19–2562 (3rd Cir. August 27, 2020). None of the sources in this proposed rulemaking are subject to the presumptive RACT II provisions at issue in the *Sierra Club* decision.

TABLE 2—FOURTEEN MAJOR NO_X AND/OR VOC SOURCES IN PENNSYLVANIA SUBJECT TO CASE–BY–CASE RACT II UNDER THE 1997 AND 2008 8-HOUR OZONE NAAQS

Major source (county)	1-Hour ozone RACT source? (RACT I)	Major source pollutant (NO_X and/or VOC)	RACT II permit (effective date)
Dart Container Corporation of Pennsylvania—East Lampeter (Lancaster)	Yes	VOC	36–05117 (10/15/2020)
Dart Container Corporation of Pennsylvania—Leola (Lancaster)	Yes	NO_X and VOC	36–05015 (03/30/2020)
Carpenter Latrobe Specialty Metals, LLC (Westmoreland)	Yes	NO_X	65–00016 (02/26/2020)
ATI Flat Rolled Products Holdings, LLC (Westmoreland)	Yes	NO_X	65–00137 (03/11/2020)
CONSOL Pennsylvania Coal Company, LLC (Greene)	Yes	VOC	30–00072L (03/12/2020)
IPSCO Koppel Tubular Corporation—IPSCO Ambridge (Beaver)	No	NO_X	04–00227 (03/26/2020)
IPSCO Koppel Tubular Corporation—IPSCO Koppel (Beaver)	Yes	NO_X and VOC	04–00059 (03/16/2020)
MarkWest Liberty Bluestone Plant (Butler)	No	VOC	10–00368 (02/20/2020)
York Group, Inc. York Casket Manufacturing (York)	Yes	VOC	67–05014C (03/04/2020)
Omnova Solutions Inc- Jeannette Plant (Westmoreland)	Yes	VOC	65–00207 (02/06/2020)
Jessop Steel LLC- Washington Plant (Washington)	Yes	NO_X	63–00027 (03/11/2020)
Kawneer Commercial Windows LLC (Butler)	Yes	VOC	10–00267 (03/04/2020)
Tennessee Gas Pipeline Co., LLC, Marienville STA 307 (Forest)	Yes	NO_X and VOC	27–015A (12/07/2018)
Mack Truck—Macungie (Lehigh)	Yes	NO_X and VOC	39–00004 (04/03/2020)

The case-by-case RACT determinations submitted by PADEP consist of an evaluation of all reasonably available controls at the time of evaluation for each affected emissions unit, resulting in a PADEP determination of what specific control requirements, if any, satisfy RACT for that particular unit. The adoption of new or additional controls or the revisions to existing controls as RACT were specified as requirements in new or revised Federally enforceable permits (hereafter RACT II permits) issued by PADEP to the source. The RACT II permits, which revise or adopt additional source-specific controls, have been submitted as part of the Pennsylvania RACT SIP revisions for EPA's approval in the Pennsylvania SIP under 40 CFR 52.2020(d)(1). The RACT II permits submitted by PADEP are listed in the last column of Table 2 of this document, along with the permit effective date, and are part of the docket for this rulemaking, which is available online at *https://www.regulations.gov,* Docket No. EPA–R03–OAR–2021–0217.[9] EPA is proposing to incorporate by reference in the Pennsylvania SIP, via the RACT II permits, source-specific RACT determinations under the 1997 and 2008 8-hour ozone NAAQS for certain sources at major NO_X and VOC emitting facilities.

[9] The RACT II permits are redacted versions of a facility's Federally enforceable permits and reflect the specific RACT requirements being approved into the Pennsylvania SIP.

III. EPA's Evaluation of SIP Revisions

After thorough review and evaluation of the information provided by PADEP for sources at fourteen major NO_X and/or VOC emitting facilities in Pennsylvania included in its SIP revision submittal, EPA finds that PADEP's case-by-case RACT determinations and conclusions provided are reasonable and appropriately considered technically and economically feasible controls, while setting lowest achievable limits. EPA finds that the proposed source-specific RACT controls for the sources subject to this rulemaking action adequately meet the CAA RACT requirements for the 1997 and 2008 8-hour ozone NAAQS for the subject sources of NO_X and/or VOC in Pennsylvania, as they are not covered by or cannot meet Pennsylvania's presumptive RACT regulation.

EPA also finds that all the proposed revisions to previously SIP approved RACT requirements, under the 1979 1-hour ozone standard (RACT I), as discussed in PADEP's SIP revisions, will result in equivalent or additional reductions of NO_X and/or VOC emissions and should not interfere with any applicable requirement concerning attainment or reasonable further progress with the NAAQS or interfere with other applicable CAA requirement in section 110(l) of the CAA.

EPA's complete analysis of PADEP's case-by-case RACT SIP revisions is included in the TSD available in the docket for this rulemaking action and available online at *https://www.regulations.gov,* Docket number EPA–R03–OAR–2021–0217.

IV. Proposed Action

Based on EPA's review, EPA is proposing to approve the Pennsylvania SIP revisions for case-by-case RACT determinations for individual sources at fourteen major NO_X and VOC emitting facilities listed in Table 2 of this document and incorporate by reference in the Pennsylvania SIP, via the RACT II permits, source specific RACT determinations under the 1997 and 2008 8-hour ozone NAAQS for those sources. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action. As EPA views each facility as a separable SIP revision, should EPA receive comment on one

facility but not others, EPA may take separate, final action on the remaining facilities.

V. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference source specific RACT determinations via the RACT II permits as described in Sections II and III—Summary of SIP Revisions and EPA's Evaluation of SIP Revisions. EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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 CAA. Accordingly, this 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 proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- 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 CAA; 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 proposed rulemaking, addressing the Pennsylvania NO_X and VOC RACT case-by-case requirements for individual sources at fourteen facilities for the 1997 and 2008 8-hour ozone NAAQS, 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, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 26, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

[FR Doc. 2021–16284 Filed 7–30–21; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2021–0380; FRL–8694–01–R3]

Approval and Promulgation of Air Quality Plans; Pennsylvania; Reasonably Available Control Technology (RACT) Determinations for Case-by-Case Sources Under the 1997 and 2008 8-Hour Ozone National Ambient Air Quality Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve multiple state implementation plan (SIP) revisions submitted by the Commonwealth of Pennsylvania. These revisions were submitted by the Pennsylvania Department of Environmental Protection (PADEP) to establish and require reasonably available control technology (RACT) for twenty-four major sources of volatile organic compounds (VOC) and/or nitrogen oxides (NO_X) pursuant to the Commonwealth of Pennsylvania's conditionally approved RACT regulations. In this rulemaking action, EPA is proposing to approve source-specific (also referred to as ''case-by-case'') RACT determinations for sources at twenty-four major NO_X and VOC emitting facilities submitted by PADEP. These RACT evaluations were submitted to meet RACT requirements for the 1997 and 2008 8-hour ozone national ambient air quality standards (NAAQS). This action is being taken under the Clean Air Act (CAA).

DATES: Written comments must be received on or before September 1, 2021.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R03–OAR–2021–0380 at *https://www.regulations.gov,* or via email to *opila.marycate@epa.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* For either manner of submission, EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be confidential business information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Mr. Riley Burger, Permits Branch (3AD10), Air & Radiation Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. The telephone number is (215) 814–2217.

Mr. Burger can also be reached via electronic mail at *burger.riley@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 7, 2020, PADEP submitted a revision to its SIP to address case-by-case NO_X and/or VOC RACT for sources at numerous major NO_X and VOC emitting facilities located in the Commonwealth, including the twenty-four facilities in this action. This SIP revision is intended to address the NO_X and/or VOC RACT requirements under sections 182 and 184 of the CAA for the 1997 and 2008 8-hour ozone NAAQS. Table 1 of this document lists the SIP submittal date and the facilities included in PADEP's submittal. Although submitted in one SIP revision by PADEP, EPA views each facility as a separable SIP revision and may take separate final action on one or more facilities.

For additional background information on Pennsylvania's ''presumptive'' RACT II SIP see 84 FR 20274 (May 9, 2019) and on Pennsylvania's source-specific or ''case-by-case'' RACT determinations see the appropriate technical support document (TSD) which is available online at *https://www.regulations.gov,* Docket No. EPA–R03–OAR–2021–0380.

TABLE 1—PADEP SIP SUBMITTALS FOR MAJOR NO_X AND/OR VOC SOURCES IN PENNSYLVANIA SUBJECT TO SOURCE-SPECIFIC RACT UNDER THE 1997 AND 2008 8-HOUR OZONE STANDARD

SIP submittal date	Major source (county)
5/7/2020	Anvil International, LLC (formerly Grinnell Corporation) (Lancaster). ArcelorMittal Plate LLC Conshohocken Plant (formerly Bethlehem Lukens Plate) (Montgomery). Braskem America Inc. Marcus Hook (formerly Epsilon Products Co.—Marcus Hook) (Delaware). Buck Co Inc. Quarryville (formerly Buck Company Inc) (Lancaster). Calumet Karns City Refining LLC (formerly Penreco—Karns City) (Butler). Clarion Bathware Marble (Clarion). Domtar Paper Company Johnsonburg Mill (formerly Willamette Industries, Johnsonburgh Mill) (Elk). Exelon Generation Company LLC Croydon Generating Station (formerly PECO Energy Co.—Croydon Generating Station) (Bucks). Georgia-Pacific Panel Products LLC Mt. Jewell MDF Plant (McKean). GE Transportation Grove City Engine (formerly GE Transportation Systems) (Mercer). GrafTech USA LLC St Marys (formerly The Carbide/Graphite Group, Inc) (Elk). Haysite Reinforced Plastics LLC Erie (Erie). INMETCO Ellwood City (formerly The International Metals Reclamation Co) (Lawrence). International Waxes Inc Farmers Valley (formerly Petrowax Refining) (McKean). Jeld Wen Fiber Division PA (Bradford). Mars Wrigley Confectionery US LLC Elizabethtown (Lancaster). Molded Fiber Glass Company Union City (formerly Molded Fiber Glass) (Erie). Monroe Energy LLC Trainer (formerly Conoco Phillips Company) (Delaware). Nova Chemicals Company Beaver (formerly Nova Chemicals, Inc.) (Beaver). Sasol Chemicals USA LLC (formerly Merisol Antioxidants LLC) (Venango). Silberline Manufacturing Company Lincoln Drive Plant (formerly Silberline Manufacturing Co) (Schuylkill). Superior Tube Company Lower Providence (formerly Superior Tube Company) (Montgomery). Victaulic Company Alburtis Facility (Lehigh). Victaulic Forks Facility (Northampton).

I. Background

A. 1997 and 2008 8-Hour Ozone NAAQS

Ground level ozone is not emitted directly into the air but is created by chemical reactions between NO_X and VOC in the presence of sunlight. Emissions from industrial facilities, electric utilities, motor vehicle exhaust, gasoline vapors, and chemical solvents are some of the major sources of NO_X and VOC. Breathing ozone can trigger a variety of health problems, particularly for children, the elderly, and people of all ages who have lung diseases such as asthma. Ground level ozone can also have harmful effects on sensitive vegetation and ecosystems.

On July 18, 1997, EPA promulgated a standard for ground level ozone based on 8-hour average concentrations. 62 FR 38856. The 8-hour averaging period replaced the previous 1-hour averaging period, and the level of the NAAQS was changed from 0.12 parts per million (ppm) to 0.08 ppm. EPA has designated two moderate nonattainment areas in Pennsylvania under the 1997 8-hour ozone NAAQS, namely Philadelphia-Wilmington-Atlantic City, PA-NJ-MD-DE (the Philadelphia Area) and Pittsburgh-Beaver Valley (the Pittsburgh Area). See 40 CFR 81.339.

On March 12, 2008, EPA strengthened the 8-hour ozone standards, by revising its level to 0.075 ppm averaged over an 8-hour period (2008 8-hour ozone NAAQS). On May 21, 2012, EPA designated five marginal nonattainment areas in Pennsylvania for the 2008 8-hour ozone NAAQS: Allentown-Bethlehem-Easton, Lancaster, Reading, the Philadelphia Area, and the Pittsburgh Area. 77 FR 30088; see also 40 CFR 81.339.

On March 6, 2015, EPA announced its revocation of the 1997 8-hour ozone NAAQS for all purposes and for all areas in the country, effective on April 6, 2015. 80 FR 12264. EPA has determined that certain nonattainment planning requirements continue to be in effect under the revoked standard for nonattainment areas under the 1997 8-hour ozone NAAQS, including RACT.

B. RACT Requirements for Ozone

The CAA regulates emissions of NO_X and VOC to prevent photochemical reactions that result in ozone formation. RACT is an important strategy for reducing NO_X and VOC emissions from major stationary sources within areas not meeting the ozone NAAQS.

Areas designated nonattainment for the ozone NAAQS are subject to the general nonattainment planning requirements of CAA section 172. Section 172(c)(1) of the CAA provides that SIPs for nonattainment areas must include reasonably available control measures (RACM) for demonstrating attainment of all NAAQS, including emissions reductions from existing sources through the adoption of RACT. Further, section 182(b)(2) of the CAA sets forth additional RACT requirements

for ozone nonattainment areas classified as moderate or higher. Section 182(b)(2) of the CAA sets forth requirements regarding RACT for the ozone NAAQS for VOC sources. Section 182(f) subjects major stationary sources of NO_X to the same RACT requirements applicable to major stationary sources of VOC.[1]

Section 184(b)(1)(B) of the CAA applies the RACT requirements in section 182(b)(2) to nonattainment areas classified as marginal and to attainment areas located within ozone transport regions established pursuant to section 184 of the CAA. Section 184(a) of the CAA established by law the current Ozone Transport Region (OTR) comprised of 12 eastern states, including Pennsylvania. This requirement is referred to as OTR RACT. As noted previously, a ''major source'' is defined based on the source's potential to emit (PTE) of NO_X, VOC, or both pollutants, and the applicable thresholds differ based on the classification of the nonattainment area in which the source is located. See sections 182(c)–(f) and 302 of the CAA.

Since the 1970's, EPA has consistently defined ''RACT'' as the lowest emission limit that a particular source is capable of meeting by the application of the control technology that is reasonably available considering technological and economic feasibility.[2]

EPA has provided more substantive RACT requirements through implementation rules for each ozone NAAQS as well as through guidance. In 2004 and 2005, EPA promulgated an implementation rule for the 1997 8-hour ozone NAAQS in two phases (''Phase 1 of the 1997 Ozone Implementation Rule'' and ''Phase 2 of the 1997 Ozone Implementation Rule''). 69 FR 23951 (April 30, 2004) and 70 FR 71612 (November 29, 2005), respectively. Particularly, the Phase 2 Ozone Implementation Rule addressed RACT statutory requirements under the 1997 8-hour ozone NAAQS. See 70 FR 71652 (November 29, 2005).

On March 6, 2015, EPA issued its final rule for implementing the 2008 8-hour ozone NAAQS (''the 2008 Ozone SIP Requirements Rule''). 80 FR 12264. At the same time, EPA revoked the 1997 8-hour ozone NAAQS, effective on April 6, 2015.[3] The 2008 Ozone SIP Requirements Rule provided comprehensive requirements to transition from the revoked 1997 8-hour ozone NAAQS to the 2008 8-hour ozone NAAQS, as codified in 40 CFR part 51, subpart AA, following revocation. Consistent with previous policy, EPA determined that areas designated nonattainment for both the 1997 and 2008 8-hour ozone NAAQS at the time of revocation, must retain implementation of certain nonattainment area requirements (*i.e.,* anti-backsliding requirements) for the 1997 8-hour ozone NAAQS as specified under section 182 of the CAA, including RACT. See 40 CFR 51.1100(o). An area remains subject to the anti-backsliding requirements for a revoked NAAQS until EPA approves a redesignation to attainment for the area for the 2008 8-hour ozone NAAQS. There are no effects on applicable requirements for areas within the OTR, as a result of the revocation of the 1997 8-hour ozone NAAQS. Thus, Pennsylvania, as a state within the OTR, remains subject to RACT requirements for both the 1997 8-hour ozone NAAQS and the 2008 8-hour ozone NAAQS.

In addressing RACT, the 2008 Ozone SIP Requirements Rule is consistent with existing policy and Phase 2 of the 1997 Ozone Implementation Rule. In the 2008 Ozone SIP Requirements Rule, EPA requires RACT measures to be implemented by January 1, 2017 for areas classified as moderate nonattainment or above and all areas of the OTR. EPA also provided in the 2008 Ozone SIP Requirements Rule that RACT SIPs must contain adopted RACT regulations, certifications where appropriate that existing provisions are RACT, and/or negative declarations stating that there are no sources in the nonattainment area covered by a specific control technique guidelines (CTG) source category. In the preamble to the 2008 Ozone SIP Requirements Rule, EPA clarified that states must provide notice and opportunity for public comment on their RACT SIP submissions, even when submitting a certification that the existing provisions remain RACT or a negative declaration. States must submit appropriate supporting information for their RACT submissions, in accordance with the Phase 2 of the 1997 Ozone Implementation Rule. Adequate documentation must support that states have considered control technology that is economically and technologically feasible in determining RACT, based on information that is current as of the time of development of the RACT SIP.

In addition, in the 2008 Ozone SIP Requirements Rule, EPA clarified that states can use weighted average NO_X emissions rates from sources in the nonattainment area for meeting the major NO_X RACT requirement under the CAA, as consistent with existing policy.[4] EPA also recognized that states may conclude in some cases that sources already addressed by RACT determinations for the 1979 1-hour and/or 1997
8-hour ozone NAAQS may not need to implement additional controls to meet the 2008
8-hour ozone NAAQS RACT requirement. See 80 FR 12278 and 12279 (March 6, 2015).

C. Applicability of RACT Requirements in Pennsylvania

As indicated earlier, RACT requirements apply to any ozone nonattainment areas classified as moderate or higher (serious, severe or extreme) under CAA sections 182(b)(2) and 182(f). Pennsylvania has outstanding ozone RACT requirements for both the 1997 and 2008 8-hour ozone NAAQS. The entire Commonwealth of Pennsylvania is part of the OTR established under section 184 of the CAA and thus is subject statewide to the RACT requirements of CAA sections 182(b)(2) and 182(f), pursuant to section 184(b).

At the time of revocation of the 1997 8-hour ozone NAAQS (effective April 6, 2015), only two moderate nonattainment areas remained in the Commonwealth of Pennsylvania for this standard, the Philadelphia and the Pittsburgh Areas. As required under EPA's anti-backsliding provisions, these

[1] A ''major source'' is defined based on the source's potential to emit (PTE) of NO_X or VOC, and the applicable thresholds for RACT differs based on the classification of the nonattainment area in which the source is located. See sections 182(c)–(f) and 302 of the CAA.

[2] See December 9, 1976 memorandum from Roger Strelow, Assistant Administrator for Air and Waste Management, to Regional Administrators, ''Guidance for Determining Acceptability of SIP Regulations in Non-Attainment Areas,'' and also 44 FR 53762 (September 17, 1979).

[3] On February 16, 2018, the United States Court of Appeals for the District of Columbia Circuit (D.C. Cir. Court) issued an opinion on the 2008 Ozone SIP Requirements Rule. *South Coast Air Quality Mgmt. Dist.* v. *EPA,* 882 F.3d 1138 (D.C. Cir. 2018). The D.C. Cir. Court found certain parts reasonable and denied the petition for appeal on those. In particular, the D.C. Cir. Court upheld the use of NO_X averaging to meet RACT requirements for 2008 8-hour ozone NAAQS. However, the Court also found certain other provisions unreasonable. The D.C. Cir. Court vacated the provisions it found unreasonable.

[4] EPA's NO_X RACT guidance ''Nitrogen Oxides Supplement to the General Preamble'' (57 FR 55620; November 25, 1992) encouraged states to develop RACT programs that are based on ''area wide average emission rates.'' Additional guidance on area-wide RACT provisions is provided by EPA's January 2001 economic incentive program guidance titled ''Improving Air Quality with Economic Incentive Programs,'' available at *https://www.epa.gov/sites/production/files/2015-07/documents/eipfin.pdf.* In addition, as mentioned previously, the D.C. Cir. Court upheld the use of NO_X averaging to meet RACT requirements for 2008 8-hour ozone NAAQS. *South Coast Air Quality Mgmt. Dist.* v. *EPA,* No. 15–1115 (D.C. Cir. February 16, 2018).

two moderate nonattainment areas continue to be subject to RACT under the 1997 8-hour ozone NAAQS. Given its location in the OTR, the remainder of the Commonwealth is also treated as moderate nonattainment area under the 1997 8-hour ozone NAAQS for any planning requirements under the revoked standard, including RACT. The OTR RACT requirement is also in effect under the 2008 8-hour ozone NAAQS throughout the Commonwealth, since EPA did not designate any nonattainment areas above marginal for this standard in Pennsylvania. Thus, in practice, the same RACT requirements continue to be applicable in Pennsylvania for both the 1997 and 2008 8-hour ozone NAAQS. RACT must be evaluated and satisfied as separate requirements under each applicable standard.

RACT applies to major sources of NO_X and VOC under each ozone NAAQS or any VOC sources subject to CTG RACT. Which NO_X and VOC sources in Pennsylvania are considered ''major'' and are therefore subject to RACT is dependent on the location of each source within the Commonwealth. Sources located in nonattainment areas would be subject to the ''major source'' definitions established under the CAA based on the area's current classification(s). In the case of Pennsylvania, sources located outside of moderate or above ozone nonattainment areas, as part of the OTR, shall be treated as if these areas were moderate.

In Pennsylvania, the SIP program is implemented primarily by the PADEP, but also by local air agencies in Philadelphia County (the City of Philadelphia's Air Management Services [AMS]) and Allegheny County, (the Allegheny County Health Department [ACHD]). These agencies have implemented numerous RACT regulations and source-specific measures in Pennsylvania to meet the applicable ozone RACT requirements. Historically, statewide RACT controls have been promulgated by PADEP in Pennsylvania Code Title 25—Environmental Resources, Part I—Department of Environmental Protection, Subpart C—Protection of Natural Resources, Article III—Air Resources, (25 Pa. Code) Chapter 129. AMS and ACHD have incorporated by reference Pennsylvania regulations, but have also promulgated regulations adopting RACT controls for their own jurisdictions. In addition, AMS and ACHD have submitted, through PADEP, separate source-specific RACT determinations as SIP revisions for sources within their respective jurisdictions, which have been approved by EPA. See 40 CFR 52.2020(d)(1).

States were required to make RACT SIP submissions for the 1997 8-hour ozone NAAQS by September 15, 2006. PADEP submitted a SIP revision on September 25, 2006, certifying that a number of previously approved VOC RACT rules continued to satisfy RACT under the 1997 8-hour ozone NAAQS for the remainder of Pennsylvania.[5] PADEP has met its obligations under the 1997 8-hour ozone NAAQS for its CTG and non-CTG VOC sources. See 82 FR 31464 (July 7, 2017). RACT control measures addressing all applicable CAA RACT requirements under the 1997 8-hour ozone NAAQS have been implemented and fully approved in the jurisdictions of ACHD and AMS. See 78 FR 34584 (June 10, 2013) and 81 FR 69687 (October 7, 2016). For the 2008 8-hour ozone NAAQS, states were required to submit RACT SIP revisions by July 20, 2014. On May 16, 2016, PADEP submitted a SIP revision addressing RACT for both the 1997 and 2008 8-hour ozone NAAQS in Pennsylvania. Specifically, the May 16, 2016 SIP submittal intended to satisfy sections 182(b)(2)(C), 182(f), and 184 of the CAA for both the 1997 and 2008 8-hour ozone NAAQS for Pennsylvania's major NO_X and VOC non-CTG sources, except ethylene production plants, surface active agents manufacturing, and mobile equipment repair and refinishing.[6]

D. EPA's Conditional Approval for Pennsylvania's RACT Requirements Under the 1997 and 2008 8-Hour Ozone NAAQS

On May 16, 2016, PADEP submitted a SIP revision addressing RACT for both the 1997 and 2008 8-hour ozone NAAQS in Pennsylvania. PADEP's May 16, 2016 SIP revision intended to address certain outstanding VOC CTG RACT and major NO_X RACT requirements under the CAA for both standards. The SIP revision requested approval of Pennsylvania's 25 Pa. Code 129.96–100, *Additional RACT Requirements for Major Sources of NO_X and VOCs* (the ''presumptive'' RACT II rule). Prior to the adoption of the RACT II rule, Pennsylvania relied on the NO_X and VOC control measures in 25 Pa. Code 129.92–95, *Stationary Sources of NO_X and VOCs,* (the RACT I rule) to meet RACT for major sources of VOC and NO_X. The requirements of the RACT I rule remain in effect and continue to be implemented as RACT.[7] On September 26, 2017, PADEP submitted a supplemental SIP revision which committed to address various deficiencies identified by EPA in PADEP's May 16, 2016 ''presumptive'' RACT II rule SIP revision.

On May 9, 2019, EPA conditionally approved the RACT II rule based on PADEP's September 26, 2017 commitment letter.[8] See 84 FR 20274. In EPA's final conditional approval, EPA noted that PADEP would be required to submit, for EPA's approval, SIP revisions to address any facility-wide or system-wide averaging plan approved under 25 Pa. Code 129.98 and any case-by-case RACT determinations under 25 Pa. Code 129.99. PADEP committed to submitting these additional SIP revisions within 12 months of EPA's final conditional approval, specifically May 9, 2020.

Therefore, as authorized in CAA section 110(k)(3) and (k)(4), Pennsylvania was required to submit the following as case-by-case SIP revisions, by May 9, 2020, for EPA's approval as a condition of approval of 25 Pa. Code 128 and 129 in the May 16, 2016 SIP revision: (1) All facility-wide or system-wide averaging plans approved by PADEP under 25 Pa. Code 129.98 including, but not limited to, any terms and conditions that ensure the enforceability of the averaging plan as a practical matter (*i.e.,* any monitoring, reporting, recordkeeping, or testing requirements); and (2) all source-specific RACT determinations approved by PADEP under 25 Pa. Code 129.99, including any alternative compliance schedules approved under 25 Pa. Code 129.97(k) and 129.99(i); the case-by-case RACT determinations submitted to EPA for approval into the SIP should include any terms and conditions that ensure the enforceability of the case-by-case or source-specific RACT emission limitation as a practical matter (*i.e.,* any monitoring, reporting, recordkeeping, or testing requirements). See May 9, 2019 (84 FR 20274). Through multiple

[5] The September 15, 2006 SIP submittal initially included Pennsylvania's certification of NO_X RACT regulations; however, NO_X RACT portions were withdrawn by PADEP on June 27, 2016.

[6] EPA's conditional approval of PADEP's May 16, 2016 SIP revision covered relevant sources located in both Philadelphia and Allegheny County, Pennsylvania.

[7] These requirements were initially approved as RACT for Pennsylvania under the 1979 1-hour ozone NAAQS. The RACT I Rule was approved by EPA into the SIP on March 23, 1998. 63 FR 13789.

[8] On August 27, 2020, the Third Circuit Court of Appeals issued a decision vacating EPA's approval of three provisions of Pennsylvania's presumptive RACT II rule applicable to certain coal-fired power plants. *Sierra Club* v. *EPA,* No. 19–2562 (3rd Cir. August 27, 2020). None of the sources in this proposed rulemaking are subject to the three presumptive RACT II provisions at issue in that *Sierra Club* decision.

submissions between 2017 and 2020, PADEP has submitted to EPA for approval various SIP submissions to implement its RACT II case-by-case determinations and averaging plans. This proposed rulemaking is based on EPA's review of one of these SIP revisions.

II. Summary of SIP Revisions

In order to satisfy a requirement from EPA's May 9, 2019 conditional approval, PADEP has submitted to EPA, SIP revisions addressing case-by-case RACT requirements for major sources in Pennsylvania subject to 25 Pa. Code 129.99. As noted in Table 1 of this document, on May 7 2020, PADEP submitted to EPA, a SIP revision pertaining to Pennsylvania's case-by-case NO_X and/or VOC RACT determinations for sources located at numerous major NO_X and VOC emitting facilities located in the Commonwealth. PADEP provided documentation in its SIP revisions to support its case-by-case RACT determinations for affected emission units at each major NO_X and VOC emitting facilities subject to 25 Pa. Code 129.99.

In the Pennsylvania RACT SIP revision, PADEP included a case-by-case RACT determination for the existing emissions units at each of these major sources of NO_X and/or VOC that required a source specific RACT determination. In PADEP's RACT determinations an evaluation was completed to determine if previously SIP-approved, case-by-case RACT requirements (herein referred to as RACT I) were more stringent and required to be retained in the sources Title V air quality permit and subsequently, the Federally-approved SIP, or if the new case-by-case RACT requirements are more stringent and supersede the previous Federally-approved provisions.

EPA, in this action, is taking action on sources at twenty-four major NO_X and/or VOC emitting facilities in Pennsylvania, subject to Pennsylvania's case-by-case RACT requirements, as summarized in Table 2.

TABLE 2—TWENTY-FOUR MAJOR NO_X AND/OR VOC SOURCES IN PENNSYLVANIA SUBJECT TO CASE-BY-CASE RACT II UNDER THE 1997 AND 2008 8-HOUR OZONE NAAQS

Major source (county)	1-Hour ozone RACT source? (RACT I)	Major source pollutant (NO_X and/or VOC)	RACT II permit (effective date)
Anvil International, LLC (formerly Grinnell Corporation) (Lancaster)	Yes	VOC	36–05019 (2/1/2019)
ArcelorMittal Plate LLC Conshohocken Plant (formerly Bethlehem Lukens Plate) (Montgomery).	Yes	NO_X and VOC	46–00011 (1/26/2018)
Braskem America Inc. Marcus Hook (formerly Epsilon Products Co.—Marcus Hook) (Delaware).	Yes	VOC	23–00012 (3/2/2020)
Buck Co Inc. Quarryville (formerly Buck Company Inc) (Lancaster)	Yes	VOC	36–05053 (4/1/2020)
Calumet Karns City Refining LLC (formerly Penreco—Karns City) (Butler)	Yes	VOC	10–027H (11/29/2018)
Clarion Bathware Marble (Clarion)	No	VOC	16–00133 (12/19/2020)
Domtar Paper Company Johnsonburg Mill (formerly Willamette Industries, Johnsonburgh Mill) (Elk).	Yes	NO_X and VOC	24–00009 (2/25/2020)
Exelon Generation Company LLC Croydon Generating Station (formerly PECO Energy Co.—Croydon Generating Station) (Bucks).	Yes	NO_X	09–00016 (4/11/2018)
Georgia-Pacific Panel Products LLC Mt. Jewell MDF Plant (McKean)	Yes	NO_X and VOC	42–158R (1/2/2019)
GE Transportation Grove City Engine (formerly GE Transportation Systems) (Mercer)	Yes	NO_X and VOC	43–00196 (11/7/2019)
GrafTech USA LLC St Marys (formerly The Carbide/Graphite Group, Inc) (Elk)	Yes	VOC	24–00012 (5/1/2019)
Haysite Reinforced Plastics LLC Erie (Erie)	No	VOC	25–00783 (7/24/2019)
INMETCO Ellwood City (formerly The International Metals Reclamation Co) (Lawrence)	Yes	NO_X and VOC	37–00243 (12/6/2019)
International Waxes Inc Farmers Valley (formerly Petrowax Refining) (McKean)	Yes	NO_X and VOC	42–00011 (2/21/2020)
Jeld Wen Fiber Division PA (Bradford)	Yes	NO_X and VOC	08–00003 (9/21/2018)
Mars Wrigley Confectionery US LLC Elizabethtown (Lancaster)	Yes	VOC	36–05142 (7/18/2019)
Molded Fiber Glass Company Union City (formerly Molded Fiber Glass) (Erie)	Yes	VOC	25–00035 (2/5/2020)
Monroe Energy LLC Trainer (formerly Conoco Phillips Company) (Delaware)	Yes	NO_X and VOC	23–00003 (6/5/2017)
Nova Chemicals Company Beaver (formerly Nova Chemicals, Inc.) (Beaver)	Yes	VOC	04–00033 (4/2/2020)
Sasol Chemicals USA LLC (formerly Merisol Antioxidants LLC) (Venango)	Yes	VOC	61–00011 (2/16/2020)
Silberline Manufacturing Company Lincoln Drive Plant (formerly Silberline Manufacturing Co) (Schuylkill).	Yes	VOC	54–00041 (3/16/2020)
Superior Tube Company Lower Providence (formerly Superior Tube Company) (Montgomery).	Yes	VOC	46–00020 (2/5/2020)
Victaulic Company Alburtis Facility (Lehigh)	Unknown *	VOC	39–00069 (10/24/2017)

TABLE 2—TWENTY-FOUR MAJOR NO_X AND/OR VOC SOURCES IN PENNSYLVANIA SUBJECT TO CASE-BY-CASE RACT II UNDER THE 1997 AND 2008 8-HOUR OZONE NAAQS—Continued

Major source (county)	1-Hour ozone RACT source? (RACT I)	Major source pollutant (NO_X and/or VOC)	RACT II permit (effective date)
Victaulic Forks Facility (Northampton)	Unknown **	VOC	48–0009 (10/24/2017)

* PADEP records indicate that Victaulic Company Alburtis Facility may have been subject to RACT I requirements because PADEP technical review memos and operating permits issued to the facility in the past reference RACT I requirements. However, in reviewing the facility's files, PADEP could not produce a RACT I permit nor any files specific to the issuance of RACT I. Furthermore, RACT I requirements were never incorporated into the Pennsylvania SIP for Victaulic Alburtis. See PADEP comment and response document dated January 2020.

** PADEP records indicate that Victaulic Forks Facility may have been subject to RACT I requirements because PADEP technical review memos and operating permits issued to the facility in the past reference RACT I requirements. However, in reviewing the facility's files, PADEP could not produce a RACT I permit nor any files specific to the issuance of RACT I. Furthermore, RACT I requirements were never incorporated into the Pennsylvania SIP for Victaulic Forks. See PADEP comment and response document dated January 2020.

The case-by-case RACT determinations submitted by PADEP consist of an evaluation of all reasonably available controls at the time of evaluation for each affected emissions unit, resulting in a PADEP determination of what specific control requirements, if any, satisfy RACT for that particular unit. The adoption of new or additional controls or the revisions to existing controls as RACT were specified as requirements in new or revised Federally enforceable permits (hereafter RACT II permits) issued by PADEP to the source. The RACT II permits, which revise or adopt additional source-specific controls, have been submitted as part of the Pennsylvania RACT SIP revisions for EPA's approval in the Pennsylvania SIP under 40 CFR 52.2020(d)(1). The RACT II permits submitted by PADEP are listed in the last column of Table 2 of this document, along with the permit effective date, and are part of the docket for this rulemaking, which is available online at *https://www.regulations.gov,* Docket No. EPA–R03–OAR–2021–0380.[9] EPA is proposing to incorporate by reference in the Pennsylvania SIP, via the RACT II permits, source-specific RACT determinations under the 1997 and 2008 8-hour ozone NAAQS for certain sources at major NO_X and VOC emitting facilities.[10]

III. EPA's Evaluation of SIP Revisions

After thorough review and evaluation of the information provided by PADEP for sources at twenty-four major NO_X and/or VOC emitting facilities in Pennsylvania included in its SIP revision submittal, EPA finds that PADEP's case-by-case RACT determinations and conclusions provided are reasonable and appropriately considered technically and economically feasible controls, while setting lowest achievable limits. EPA finds that the proposed source-specific RACT controls for the sources subject to this rulemaking action adequately meet the CAA RACT requirements for the 1997 and 2008 8-hour ozone NAAQS for the subject sources of NO_X and/or VOC in Pennsylvania, as they are not covered by or cannot meet Pennsylvania's presumptive RACT regulation.

EPA also finds that all the proposed revisions to previously SIP approved RACT requirements, under the 1979 1-hour ozone standard (RACT I), as discussed in PADEP's SIP revisions, will result in equivalent or additional reductions of NO_X and/or VOC emissions and should not interfere with any applicable requirement concerning attainment or reasonable further progress with the NAAQS or interfere with other applicable CAA requirement in section 110(l) of the CAA.

EPA's complete analysis of PADEP's case-by-case RACT SIP revisions is included in the TSD available in the docket for this rulemaking action and available online at *https://www.regulations.gov,* Docket number EPA–R03–OAR–2021–0380.

IV. Proposed Action

Based on EPA's review, EPA is proposing to approve the Pennsylvania SIP revisions for case-by-case RACT determinations for individual sources at twenty-four major NO_X and VOC emitting facilities listed in Table 2 of this document and incorporate by reference in the Pennsylvania SIP, via the RACT II permits, source specific RACT determinations under the 1997 and 2008 8-hour ozone NAAQS for those sources. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action. As EPA views each facility as a separable SIP revision, should EPA receive comment on one facility but not others, EPA may take separate, final action on the remaining facilities.

V. Incorporation by Reference

In this document, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference source specific RACT determinations via the RACT II permits as described in Sections II and III—Summary of SIP Revisions and EPA's Evaluation of SIP Revisions in this document. EPA has made, and will continue to make, these materials generally available through *https://www.regulations.gov* and at the EPA Region III Office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA 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 CAA. Accordingly, this 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 proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735,

[9] The RACT II permits are redacted versions of a facility's Federally enforceable permits and reflect the specific RACT requirements being approved into the Pennsylvania SIP.

[10] While the prior SIP-approved RACT I permit will remain part of the SIP, this RACT II rule will incorporate by reference the RACT II requirements through the RACT II permit and clarify the ongoing applicability of specific conditions in the RACT I permit.

October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

- 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 CAA; 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 proposed rulemaking, addressing the NO_X and VOC RACT case-by-case requirements for individual sources at twenty-four facilities in Pennsylvania for the 1997 and 2008 8-hour ozone NAAQS, 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, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: July 22, 2021.

Diana Esher,

Acting Regional Administrator, Region III.

[FR Doc. 2021–16279 Filed 7–30–21; 8:45 am]

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Notices

Federal Register
Vol. 86, No. 145
Monday, August 2, 2021

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

Submission for OMB Review; Comment Request

July 28, 2021.

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; 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 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.

Comments regarding this information collection received by September 1, 2021 will be considered. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Food Safety and Inspection Service

Title: Consumer Complaint Monitoring System.

OMB Control Number: 0583–0133.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and the Egg Product Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged. FSIS tracks consumer complaints about meat, poultry, and egg products. Consumer complaints are usually filed because food made the consumer sick, caused an allergic reaction, was not properly labeled (misbranded).

Need and Use of the Information: The Consumer Complaint Monitoring System web portal is used primarily to track consumer complaints regarding meat, poultry, and egg products. FSIS will use the information collected from the web portal. To not collect the information from the web portal would reduce the effectiveness of the meat, poultry, and egg products inspection program.

Description of Respondents: Individuals or households.

Number of Respondents: 3,000.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 750.

Food Safety and Inspection Service

Title: Voluntary Recalls of Meat and Poultry Products.

OMB Control Number: 0583–0135.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*) These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged. A firm that has produced or imported meat or poultry that is adulterated or misbranded and is being distributed in commerce, may voluntarily recall the product in question. When a firm voluntarily recalls a product, FSIS will conduct a recall effectiveness check.

Need and Use of the Information: In conducting a recall, the establishment will be asks to provide FSIS with some basic information, including the identity of the recalled product, the reason for the recall, and information about the distributors and customers of the product. Industry representatives use the FSIS Form 5020–3 *FSIS Preliminary Inquiry Worksheet* to provide firm contact information and specific details regarding adulterated or misbranded product in commerce, including product identifiers, product amounts and supplemental information. Recalling firms and distributors then use the FSIS Form 5020–4 *FSIS Recall Distribution Information Template* to provide the location and contact information of consignees who received recalled product. FSIS will check on the effectiveness of the recall to ensure that all products subject to recall are accounted for. FSIS field personnel will use FSIS form 8400–4 A to determine (1) if the retail consignee received notification of the recall and (2) the number of recalled products received. FSIS field personnel will also use FSIS form 8400–4 B to verify that product held by the retail consignee was properly disposed.

Description of Respondents: Business or other for-profit.

Number of Respondents: 6,090.

Frequency of responses: Reporting: On Occasion.

Total Burden Hours: 6,600.

Food Safety and Inspection Service

Title: Animal Disposition Reporting System.

OMB Control Number: 0583–0139.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*). These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged. FSIS also inspects exotic animals and rabbits under the authority

of the Agricultural Marketing Act of 1946, as amended (7 U.S.C. 1621 *et seq.*). In accordance with 9 CFR 320.6, 381.180, 352.15, and 354.91, establishments that slaughter meat, poultry, exotic animals, and rabbits are required to maintain certain records regarding their business operations and to report this information to the Agency as required.

Need and Use of the Information: FSIS will collect information from establishments using FSIS Form 6510–7, Poultry Lot Information. Poultry establishments complete the form after each shift and submit it to the agency. FSIS uses this information to plan inspection activities, to develop sampling plans, to target establishments for testing, to develop Agency budget, and to develop reports to Congress.

Description of Respondents: Business or other for-profit.

Number of Respondents: 1,159.

Frequency of Responses: Reporting: Other (daily).

Total Burden Hours: 23.180.

Food Safety and Inspection Service

Title: Requirements to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain HACCP Plan Reassessments.

OMB Control Number: 0583–0144.

Summary of Collection: The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged. Section 11017 of the Food, Conservation, and Energy Act of 2008 (Pub. L. 110–246, 112 Stat 1651, 448–49), amended the FMIA and the PPIA by adding sections 12 and 13 to the FMIA and by amending section 10 of the PPIA (21 U.S.C. 459). These sections require official establishments that believe, they have shipped into commerce or received, misbranded, or adulterated products to notify the Secretary of Agriculture.

Need and Use of the Information: Official establishments are to document each time they reassess their HACCP plans and make the reassessments available to FSIS officials for review and copying. Official establishments are to notify the FSIS District Office that they have received or have shipped into commerce misbranded or adulterated product. The information collected will permit FSIS officials to monitor closely establishments HACCP plan reassessments and to facilitate recalls or adulterated or misbranded product.

Description of Respondents: Business or other for-profit.

Number of Respondents: 6,300.

Frequency of Responses: Reporting: On occasion.

Total Burden Hours: 9,960.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2021–16397 Filed 7–30–21; 8:45 am]

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DEPARTMENT OF AGRICULTURE

U.S. Codex Office

Codex Alimentarius Commission: Meeting of the Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance

AGENCY: U.S. Codex Office, USDA.

ACTION: Notice of public meeting and request for comments.

SUMMARY: The U.S Codex Office is sponsoring a public meeting on September 9, 2021. The objective of the public meeting is to provide information and receive public comments on agenda items and draft United States (U.S.) positions to be discussed at the 8th Session of the Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) of the Codex Alimentarius Commission, which will convene virtually, October 4–9, 2021 with the report adoption on October 13, 2021. The U.S. Manager for Codex Alimentarius and the Acting Deputy Under Secretary for Trade and Foreign Agricultural Affairs recognize the importance of providing interested parties the opportunity to obtain background information on the 8th Session of the TFAMR and to address items on the agenda.

DATES: The public meeting is scheduled for September 9, 2021, from 10:00 a.m. –12:00 p.m. EDT.

ADDRESSES: The public meeting will take place via Video Teleconference only. Documents related to the 8th Session of the TFAMR will be accessible via the internet at the following address: *http://www.fao.org/fao-who-codexalimentarius/meetings/detail/en/?meeting=TFAMR&session=8.*

Dr. Donald A. Prater, U.S. Delegate to the 8th Session of the TFAMR, invites U.S. interested parties to submit their comments electronically to the following email address: *donald.prater@fda.hhs.gov.*

Registration: Attendees must register to attend the public meeting here: *https://www.zoomgov.com/meeting/register/vJIscOqsqTIrG4XB3KA9PuFQT5y28NJF068* by September 2, 2021. Early registration is encouraged.

FOR FURTHER INFORMATION CONTACT: 8th Session of the TFAMR, contact U.S. Delegate, Dr. Donald A. Prater, *donald.prater@fda.hhs.gov,* +1 (301) 348–3007.For Further Information about the public meeting Contact: U.S. Codex Office, 1400 Independence Avenue SW, Room 4861, South Agriculture Building, Washington, DC 20250. Phone (202) 720–7760, Fax: (202) 720–3157, Email: *uscodex@usda.gov*

SUPPLEMENTARY INFORMATION:

Background

Codex was established in 1963 by two United Nations organizations, the Food and Agriculture Organization and the World Health Organization. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to protect the health of consumers and ensure fair practices in the food trade.

The Terms of Reference of the Ad hoc Codex Intergovernmental Task Force on Antimicrobial Resistance (TFAMR) are:

(i) To review and revise, as appropriate, the *Code of Practice to Minimize and Contain Antimicrobial Resistance* (CXC 61–2005) to address the entire food chain, in line with the mandate of Codex.

(ii) To consider the development of Guidance on Integrated Surveillance of Antimicrobial Resistance, taking into account the guidance developed by the WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) and relevant OIE documents.

The TFAMR is hosted by the Republic of Korea. The United States attends the TFAMR as a member country of Codex.

Issues to be Discussed at the Public Meeting: The following items on the Agenda for the 8th Session of the TFAMR will be discussed during the public meeting:

- Proposed draft revision to the *Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance* (COP)(CXC 61–2005); and
- Proposed draft Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance (GLIS).

Public Meeting: At the September 9, 2021, public meeting, draft U.S. positions on the agenda items will be

described and discussed, and attendees will have the opportunity to pose questions and offer comments. Written comments may be offered at the meeting or sent to Dr. Donald A. Prater, U.S. Delegate for the 8th Session of the TFAMR (see **ADDRESSES**). Written comments should state that they relate to activities of the 8th Session of the TFAMR.

Additional Public Notification: Public awareness of all segments of rulemaking and policy development is important. Consequently, the U.S. Codex Office will announce this **Federal Register** publication on-line through the USDA web page located at: *http://www.usda.gov/*codex, a link that also offers an email subscription service providing access to information related to Codex. Customers can add or delete their subscriptions themselves and have the option to password protect their accounts.

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Mail: U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW, Washington, DC 20250–9410.

Fax: (202) 690–7442, Email: *program.intake@usda.gov.*

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC, on July 27, 2021.

Mary Lowe,

U.S. Manager for Codex Alimentarius.

[FR Doc. 2021–16378 Filed 7–30–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Forest Service

Northern Utah Resource Advisory Committee

AGENCY: Forest Service, Agriculture (USDA).

ACTION: Notice of meeting.

SUMMARY: The Northern Utah Resource Advisory Committee (RAC) will hold a virtual meeting by phone and/or video conference. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act as well as make recommendations on recreation fee proposals for sites on Ashley and Uinta-Wasatch-Cache National Forests, consistent with the Federal Lands Recreation Enhancement Act. RAC information and meeting information can be found at the following website: *https://www.fs.usda.gov/ashley/* and *https://www.fs.usda.gov/uwcnf.*

DATES: The meeting will be held on August 25, 2021, at 6:00 p.m., Mountain Daylight Time. All RAC meetings are subject to cancellation. For status of the meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT.**

ADDRESSES: The meeting will be held virtually via telephone and/or video conference.

Written comments may be submitted as described under *Supplementary Information.* All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received upon request.

FOR FURTHER INFORMATION CONTACT: Dave Whittekiend, Designated Federal Officer (DFO), by email at *david.whittekiend@usda.gov,* 801–999–2104; Ms. Loyal Clark, by email at *loyal.clark@usda.gov,* 801–999–2113; or Don Jaques, by email at *donald.jaques@usda.gov,* 435–781–5119.

Individuals who use telecommunication devices for the hearing-impaired (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Daylight Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Review Resource Advisory Committee operating guidelines;
2. Review and approve project selection criteria and prioritization process;
3. Review and approve project scoring procedure;
4. Provide project solicitation update;
5. General questions and answers;
6. Approve meeting minutes; and
7. Schedule next meeting.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by August 18, 2021, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Ms. Loyal Clark, Uinta-Wasatch-Cache National Forest, 857 West South Jordan Parkway, South Jordan, UT 84057; or by email to *loyal.clark@usda.gov.*

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices, or other reasonable accommodation. For access to the facility or proceedings, please contact the persons listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case-by-case basis.

Dated: July 27, 2021.

Cikena Reid,

USDA Committee Management Officer.

[FR Doc. 2021–16338 Filed 7–30–21; 8:45 am]

BILLING CODE 3411–15–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meetings

AGENCY: United States Commission on Civil Rights.

ACTION: Notice of Commission public business meeting.

DATES: Friday, July 23, 2021, 12:00 p.m. EST.

ADDRESSES: Meeting to take place by telephone and is open to the public by telephone: 866–556–2439, Conference ID #: 3025132.

FOR FURTHER INFORMATION CONTACT: Angelia Rorison: 202–376–7700; *publicaffairs@usccr.gov.*

SUPPLEMENTARY INFORMATION: In accordance with the Government in

Sunshine Act (5 U.S.C. 552b), the Commission on Civil Rights is holding a meeting to discuss the Commission's business for the month of July. This business meeting is open to the public. Computer assisted real-time transcription (CART) will be provided. The web link to access CART (in English) on Friday, July 23, 2021, is *https://www.streamtext.net/player?event=USCCR.* Please note that CART is text-only translation that occurs in real time during the meeting and is not an exact transcript.

Meeting Agenda

I. Approval of Agenda
II. Business Meeting
  A. Discussion and Vote on Findings and Recommendations for the Disparities in Maternal Health Report
  B. Discussion and Vote to Confirm October 22, 2021, as FEMA Field Briefing in Houston, TX
  C. Discussion and Vote on Fiscal Year 2022 Business Meeting Calendar
  D. Discussion and Vote on Advisory Committee Appointments
  E. Presentations from Advisory Committees to the Commission on Recent Reports/Memos
  F. Management and Operations
  • Staff Director's Report
III. Adjourn Meeting

Dated: July 21, 2021.

Angelia Rorison,

USCCR Media and Communications Director.

[FR Doc. 2021–15874 Filed 7–29–21; 4:15 pm]

BILLING CODE 6335–01–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–26–2021]

Foreign-Trade Zone (FTZ) 38—Spartanburg County, South Carolina; Authorization of Production Activity; Black & Decker (U.S.), Inc. (Production and Kitting of Power Tools and Injection Molded Parts); Fort Mill, South Carolina

On March 30, 2021, Black & Decker (U.S.), Inc. submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 38M, in Fort Mill, South Carolina.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (86 FR 17771–17772, April 6, 2021). On July 28, 2021, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: July 28, 2021.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2021–16395 Filed 7–30–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

FOR FURTHER INFORMATION CONTACT: Brenda E. Brown, Office of AD/CVD Operations, Customs Liaison Unit, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230, telephone: (202) 482–4735.

Background

Each year during the anniversary month of the publication of an antidumping or countervailing duty order, finding, or suspended investigation, an interested party, as defined in section 771(9) of the Tariff Act of 1930, as amended (the Act), may request, in accordance with 19 CFR 351.213, that the Department of Commerce (Commerce) conduct an administrative review of that antidumping or countervailing duty order, finding, or suspended investigation.

All deadlines for the submission of comments or actions by Commerce discussed below refer to the number of calendar days from the applicable starting date.

Respondent Selection

In the event Commerce limits the number of respondents for individual examination for administrative reviews initiated pursuant to requests made for the orders identified below, Commerce intends to select respondents based on U.S. Customs and Border Protection (CBP) data for U.S. imports during the period of review. We intend to release the CBP data under Administrative Protective Order (APO) to all parties having an APO within five days of publication of the initiation notice and to make our decision regarding respondent selection within 35 days of publication of the initiation **Federal Register** notice. Therefore, we encourage all parties interested in commenting on respondent selection to submit their APO applications on the date of publication of the initiation notice, or as soon thereafter as possible. Commerce invites comments regarding the CBP data and respondent selection within five days of placement of the CBP data on the record of the review.

In the event Commerce decides it is necessary to limit individual examination of respondents and conduct respondent selection under section 777A(c)(2) of the Act:

In general, Commerce finds that determinations concerning whether particular companies should be ''collapsed'' (*i.e.,* treated as a single entity for purposes of calculating antidumping duty rates) require a substantial amount of detailed information and analysis, which often require follow-up questions and analysis. Accordingly, Commerce will not conduct collapsing analyses at the respondent selection phase of a review and will not collapse companies at the respondent selection phase unless there has been a determination to collapse certain companies in a previous segment of this antidumping proceeding (*i.e.,* investigation, administrative review, new shipper review or changed circumstances review). For any company subject to a review, if Commerce determined, or continued to treat, that company as collapsed with others, Commerce will assume that such companies continue to operate in the same manner and will collapse them for respondent selection purposes. Otherwise, Commerce will not collapse companies for purposes of respondent selection. Parties are requested to: (a) Identify which companies subject to review previously were collapsed; and (b) provide a citation to the proceeding in which they were collapsed. Further, if companies are requested to complete a Quantity and Value Questionnaire for purposes of respondent selection, in general each company must report volume and value data separately for itself. Parties should not include data for any other party, even if they believe they should be treated as a single entity with that other party. If a company was collapsed with another company or companies in the most recently completed segment of a proceeding where Commerce considered collapsing that entity, complete quantity and value data for that collapsed entity must be submitted.

Deadline for Withdrawal of Request for Administrative Review

Pursuant to 19 CFR 351.213(d)(1), a party that requests a review may withdraw that request within 90 days of the date of publication of the notice of initiation of the requested review. The regulation provides that Commerce may extend this time if it is reasonable to do so. Determinations by Commerce to extend the 90-day deadline will be made on a case-by-case basis.

Deadline for Particular Market Situation Allegation

Section 504 of the Trade Preferences Extension Act of 2015 amended the Act by adding the concept of particular market situation (PMS) for purposes of constructed value under section 773(e) of the Act.[1] Section 773(e) of the Act states that ''if a particular market situation exists such that the cost of materials and fabrication or other processing of any kind does not accurately reflect the cost of production in the ordinary course of trade, the administering authority may use another calculation methodology under this subtitle or any other calculation methodology.'' When an interested party submits a PMS allegation pursuant to section 773(e) of the Act, Commerce will respond to such a submission consistent with 19 CFR 351.301(c)(2)(v). If Commerce finds that a PMS exists under section 773(e) of the Act, then it will modify its dumping calculations appropriately.

Neither section 773(e) of the Act nor 19 CFR 351.301(c)(2)(v) set a deadline for the submission of PMS allegations and supporting factual information. However, in order to administer section 773(e) of the Act, Commerce must receive PMS allegations and supporting factual information with enough time to consider the submission. Thus, should an interested party wish to submit a PMS allegation and supporting new factual information pursuant to section 773(e) of the Act, it must do so no later than 20 days after submission of initial Section D responses.

Opportunity To Request a Review: Not later than the last day of August 2021,[2] interested parties may request administrative review of the following orders, findings, or suspended investigations, with anniversary dates in August for the following periods:

	Period
Antidumping Duty Proceedings	
Canada: Utility Scale Wind Towers, A–122–867	2/14/20–7/31/21
Germany:	
Seamless Line and Pressure Pipe, A–428–820	8/1/20–7/31/21
Sodium Nitrite, A–428–841	8/1/20–7/31/21
India: Finished Carbon Steel Flanges, A–533–871	8/1/20–7/31/21
Indonesia: Utility Scale Wind Towers, A–560–833	2/14/20–7/31/21
Italy: Finished Carbon Steel Flanges, A–475–835	8/1/20–7/31/21
Japan:	
Brass Sheet & Strip, A–588–704	8/1/20–7/31/21
Tin Mill Products, A–588–854	8/1/20–7/31/21
Malaysia: Polyethylene Retail Carrier Bags, A–557–813	8/1/20–7/31/21
Mexico: Light-Walled Rectangular Pipe and Tube, A–201–836	8/1/20–7/31/21
Republic of Korea:	
Dioctyl Terephthalate, A–580–889	8/1/20–7/31/21
Large Power Transformers, A–580–867	8/1/20–7/31/21
Light-Walled Rectangular Pipe and Tube, A–580–859	8/1/20–7/31/21
Low Melt Polyester Staple Fiber, A–580–895	8/1/20–7/31/21
Utility Scale Wind Towers, A–580–902	2/14/20–7/31/21
Romania: Carbon and Alloy Seamless Standard, Line, and Pressure Pipe, A–485–805 (Under 4½ Inches)	8/1/20–7/31/21
Spain: Ripe Olives, A–469–817	8/1/20–7/31/21
Socialist Republic of Vietnam:	
Frozen Fish Fillets, A–552–801	8/1/20–7/31/21
Utility Scale Wind Towers, A–552–825	2/14/20–7/31/21
Taiwan: Low Melt Polyester Staple Fiber, A–583–861	8/1/20–7/31/21
Thailand:	
Polyethylene Retail Carrier Bags, A–549–821	8/1/20–7/31/21
Steel Propane Cylinders, A–549–839	8/1/20–7/31/21
The People's Republic of China:	
Cast Iron Soil Pipe Fittings, A–570–062	8/1/20–7/31/21
Certain Steel Nails, A–570–909	8/1/20–7/31/21
Floor-Standing, Metal-Top Ironing Tables and Parts Thereof, A–570–888	8/1/20–7/31/21
Hydrofluorocarbon Blends and Components Thereof, A–570–028	8/1/20–7/31/21
Laminated Woven Sacks, A–570–916	8/1/20–7/31/21
Light-Walled Rectangular Pipe and Tube, A–570–914	8/1/20–7/31/21
Passenger Vehicle and Light Truck Tires, A–570–016	8/1/20–7/31/21
Petroleum Wax Candles, A–570–504	8/1/20–7/31/21
Polyethylene Retail Carrier Bags, A–570–886	8/1/20–7/31/21
Sodium Nitrite, A–570–925	8/1/20–7/31/21
Stainless Steel Flanges, A–570–064	8/1/20–7/31/21
Steel Propane Cylinders, A–570–086	8/1/20–7/31/21
Sulfanilic Acid, A–570–815	8/1/20–7/31/21
Tetrahydrofurfuryl Alcohol, A–570–887	8/1/20–7/31/21
Tow-Behind Lawn Groomers and Parts Thereof, A–570–939	8/1/20–7/31/21
Ukraine: Silicomanganese, A–823–805	8/1/20–7/31/21

[1] *See* Trade Preferences Extension Act of 2015, Public Law 114–27, 129 Stat. 362 (2015).

[2] Or the next business day, if the deadline falls on a weekend, federal holiday or any other day when Commerce is closed.

	Period
Countervailing Duty Proceedings	
Canada: Utility Scale Wind Towers, C–122–868	12/13/19–12/31/20
India: Finished Carbon Steel Flanges, C–533–872	1/1/20–12/31/20
Indonesia: Utility Scale Wind Towers, C–560–834	12/13/19–12/31/20
Republic of Korea: Stainless Steel Sheet and Strip in Coils, C–580–835	1/1/20–12/31/20
Spain: Ripe Olives, C–469–818	1/1/20–12/31/20
Socialist Republic of Vietnam: Utility Scale Wind Towers, C–552–826	12/13/19–12/31/20
The People's Republic of China:	
Cast Iron Soil Pipe Fittings, C–570–063	1/1/20–12/31/20
Laminated Woven Sacks, C–570–917	1/1/20–12/31/20
Light-Walled Rectangular Pipe and Tube, C–570–915	1/1/20–12/31/20
Passenger Vehicle and Light Truck Tires, C–570–017	1/1/20–12/31/20
Sodium Nitrite, C–570–926	1/1/20–12/31/20
Steel Propane Cylinders, C–570–087	1/1/20–12/31/20

Suspension Agreements

None.

In accordance with 19 CFR 351.213(b), an interested party as defined by section 771(9) of the Act may request in writing that the Secretary conduct an administrative review. For both antidumping and countervailing duty reviews, the interested party must specify the individual producers or exporters covered by an antidumping finding or an antidumping or countervailing duty order or suspension agreement for which it is requesting a review. In addition, a domestic interested party or an interested party described in section 771(9)(B) of the Act must state why it desires the Secretary to review those particular producers or exporters. If the interested party intends for the Secretary to review sales of merchandise by an exporter (or a producer if that producer also exports merchandise from other suppliers) which was produced in more than one country of origin and each country of origin is subject to a separate order, then the interested party must state specifically, on an order-by-order basis, which exporter(s) the request is intended to cover.

Note that, for any party Commerce was unable to locate in prior segments, Commerce will not accept a request for an administrative review of that party absent new information as to the party's location. Moreover, if the interested party who files a request for review is unable to locate the producer or exporter for which it requested the review, the interested party must provide an explanation of the attempts it made to locate the producer or exporter at the same time it files its request for review, in order for the Secretary to determine if the interested party's attempts were reasonable, pursuant to 19 CFR 351.303(f)(3)(ii).

As explained in *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003), and *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011), Commerce clarified its practice with respect to the collection of final antidumping duties on imports of merchandise where intermediate firms are involved. The public should be aware of this clarification in determining whether to request an administrative review of merchandise subject to antidumping findings and orders.[3]

Commerce no longer considers the non-market economy (NME) entity as an exporter conditionally subject to an antidumping duty administrative reviews.[4] Accordingly, the NME entity will not be under review unless Commerce specifically receives a request for, or self-initiates, a review of the NME entity.[5] In administrative reviews of antidumping duty orders on merchandise from NME countries where a review of the NME entity has not been initiated, but where an individual exporter for which a review was initiated does not qualify for a separate rate, Commerce will issue a final decision indicating that the company in question is part of the NME entity. However, in that situation, because no review of the NME entity was conducted, the NME entity's entries were not subject to the review and the rate for the NME entity is not subject to change as a result of that review (although the rate for the individual exporter may change as a function of the finding that the exporter is part of the NME entity). Following initiation of an antidumping administrative review when there is no review requested of the NME entity, Commerce will instruct CBP to liquidate entries for all exporters not named in the initiation notice, including those that were suspended at the NME entity rate.

All requests must be filed electronically in Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS) on Enforcement and Compliance's ACCESS website at *https://access.trade.gov.*[6] Further, in accordance with 19 CFR 351.303(f)(l)(i), a copy of each request must be served on the petitioner and each exporter or producer specified in the request. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[7]

Commerce will publish in the **Federal Register** a notice of ''Initiation of Administrative Review of Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation'' for requests received by the last day of August 2021. If Commerce does not receive, by the last day of August 2021, a request for review of entries covered by an order, finding, or suspended investigation listed in this notice and for the period identified above, Commerce will instruct CBP to assess antidumping or countervailing duties on those entries at a rate equal to the cash deposit of estimated antidumping or countervailing duties required on those entries at the time of entry, or

[3] *See* the Enforcement and Compliance website at *https://legacy.trade.gov/enforcement/.*

[4] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

[5] In accordance with 19 CFR 351.213(b)(1), parties should specify that they are requesting a review of entries from exporters comprising the entity, and to the extent possible, include the names of such exporters in their request.

[6] *See Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures,* 76 FR 39263 (July 6, 2011).

[7] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 41363 (July 10, 2020).

withdrawal from warehouse, for consumption and to continue to collect the cash deposit previously ordered.

For the first administrative review of any order, there will be no assessment of antidumping or countervailing duties on entries of subject merchandise entered, or withdrawn from warehouse, for consumption during the relevant provisional-measures ''gap'' period of the order, if such a gap period is applicable to the period of review.

This notice is not required by statute but is published as a service to the international trading community.

Dated: July 26, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–16399 Filed 7–30–21; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (Sunset) Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) is automatically initiating the five-year reviews (Sunset Reviews) of the antidumping and countervailing duty (AD/CVD) order(s) and suspended investigation(s) listed below. The International Trade Commission (ITC) is publishing concurrently with this notice its notice of *Institution of Five-Year Reviews* which covers the same order(s) and suspended investigation(s).

DATES: Applicable August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Commerce official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. For information from the ITC, contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

Commerce's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (Sunset) Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to Commerce's conduct of Sunset Reviews is set forth in *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).

Initiation of Review

In accordance with section 751(c) of the Act and 19 CFR 351.218(c), we are initiating the Sunset Reviews of the following antidumping and countervailing duty order(s) and suspended investigation(s):

DOC case No.	ITC case No.	Country	Product	Commerce contact
A–570–952	731–TA–1164	China	Narrow Woven Ribbons With Selvedge (2nd Review)	Thomas Martin; (202) 482–3936.
A–201–847	731–TA–1281	Mexico	Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes (1st Review).	Mary Kolberg; (202) 482–1785.
A–580–880	731–TA–1280	South Korea	Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes (1st Review).	Mary Kolberg; (202) 482–1785.
A–583–844	731–TA–1165	Taiwan	Narrow Woven Ribbons With Selvedge (2nd Review)	Thomas Martin; (202) 482–3936.
A–489–824	731–TA–1282	Turkey	Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes (1st Review).	Mary Kolberg; (202) 482–1785.
C–570–953	701–TA–467	China	Narrow Woven Ribbons With Selvedge (2nd Review)	Mary Kolberg; (202) 482–1785.
C–489–825	701–TA–539	Turkey	Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes (1st Review).	Mary Kolberg; (202) 482–1785.

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Commerce's regulations, Commerce's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on Commerce's website at the following address: *https://enforcement.trade.gov/sunset/.* All submissions in these Sunset Reviews must be filed in accordance with Commerce's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), can be found at 19 CFR 351.303.

In accordance with section 782(b) of the Act, any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information. Parties must use the certification formats provided in 19 CFR 351.303(g). Commerce intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), Commerce will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation. Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (APO) to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. Commerce's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306. Note that Commerce has temporarily modified certain of its requirements for serving

documents containing business proprietary information, until further notice.[1]

Information Required From Interested Parties

Domestic interested parties, as defined in sections 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with Commerce's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, Commerce will automatically revoke the order without further review.[2]

If we receive an order-specific notice of intent to participate from a domestic interested party, Commerce's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that Commerce's information requirements are distinct from the ITC 's information requirements. Consult Commerce's regulations for information regarding Commerce's conduct of Sunset Reviews. Consult Commerce's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at Commerce.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: July 21, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–16434 Filed 7–30–21; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Temporary Rule Modifying AD/CVD Service Requirements Due to* COVID–19, 85 FR 41363 (July 10, 2020).

[2] *See* 19 CFR 351.218(d)(1)(iii).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–489–815]

Light-Walled Rectangular Pipe and Tube From Turkey: Final Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) determines that there were no suspended entries of merchandise subject to the antidumping duty (AD) order on light-walled rectangular pipe and tube (LWRPT) from Turkey during the period May 1, 2019, through April 30, 2020 from any of the companies under review.

DATES: Applicable August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Thomas Hanna, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–0835.

SUPPLEMENTARY INFORMATION:

Background

On April 7, 2021, Commerce published the *Preliminary Results* of this review of the antidumping duty order on LWRPT from Turkey covering the period of review (POR) May 1, 2019, through April 30, 2020.[1] No parties commented on the *Preliminary Results.*

Scope of the Order

The merchandise subject to this order is certain welded carbon quality light-walled steel pipe and tube, of rectangular (including square) cross section, having a wall thickness of less than 4 mm. The term carbon-quality steel includes both carbon steel and alloy steel which contains only small amounts of alloying elements. Specifically, the term carbon-quality includes products in which none of the elements listed below exceeds the quantity by weight respectively indicated: 1.80 percent of manganese, or 2.25 percent of silicon, or 1.00 percent of copper, or 0.50 percent of aluminum, or 1.25 percent of chromium, or 0.30 percent of cobalt, or 0.40 percent of lead, or 1.25 percent of nickel, or 0.30 percent of tungsten, or 0.10 percent of molybdenum, or 0.10 percent of niobium, or 0.15 percent vanadium, or 0.15 percent of zirconium. The description of carbon-quality is intended to identify carbon-quality products within the scope. The welded carbon-quality rectangular pipe and tube subject to this order is currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) subheadings 7306.61.5000 and 7306.61.7060. While HTSUS subheadings are provided for convenience and CBP's customs purposes, our written description of the scope of the order is dispositive.

Analysis

Based on information obtained from U.S. Customs and Border Protection (CBP), in the *Preliminary Results* Commerce determined that, during the POR, there were no suspended U.S. entries of subject merchandise from the following companies: (1) Cinar Boru Profil Sanayi ve Ticaret A.S.; (2) Intermetal International Metal L.L.C.; (3) Parker Steel Company, Inc.; (4) Parker Steel International; (5) Tata Steel Nederland Tubes BV; and (6) Van Leeuwen Precisie B.V.[2] No parties commented on the *Preliminary Results.*

In these final results of review, we are making no changes to the *Preliminary Results.* We continue to find, based on information obtained from CBP, that during the POR, there were no suspended U.S. entries of subject merchandise from each of the six companies under review. Nevertheless, as noted in the *Preliminary Results,* we forwarded to CBP an allegation from Nucor Tubular Products Inc., a domestic interested party, that certain merchandise from the companies under review that was entered into the United States during the POR was misreported to CBP as non-subject merchandise when it may be subject merchandise.

Assessment

Upon issuance of these final results, Commerce will determine, and CBP shall assess, antidumping duties on all appropriate entries in accordance with 19 CFR 351.212(b)(1). For any entries found to be associated with the six companies under review, we will instruct CBP to liquidate such entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction, consistent with Commerce's reseller policy.[3]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of

[1] *See Light-Walled Rectangular Pipe and Tube from Turkey: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,* 86 FR 18035 (April 7, 2021) (*Preliminary Results*).

[2] *See Preliminary Results.*

[3] *See Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

publication of this notice in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all entries of LWRPT from Turkey entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice in the **Federal Register**, as provided for by section 751(a)(2)(C) of the Act: (1) If a company-specific weighted-average dumping margin was previously established in a completed segment of this proceeding for any of the six companies listed above, then the cash deposit rate will continue to be equal to the company-specific weighted-average dumping margin established for the company in the most recently completed segment (except, if the rate is *de minimis, i.e.,* less than 0.5 percent, then the cash deposit rate will be zero percent); (2) for merchandise exported by a company not covered in this review but covered in a prior completed segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for that company in the most recently completed segment of this proceeding in which the company was included; (3) if the exporter of the subject merchandise does not have its own rate but the producer has its own rate, the cash deposit rate will be the company-specific rate established in the most recently completed segment of the proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 27.04 percent, the all-others rate established in the less-than-fair-value investigation.[4]

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) 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 Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

These final results of administrative review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.213(h)(1).

Dated: July 27, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2021–16428 Filed 7–30–21; 8:45 am]

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[4] *See Notice of Final Determination of Sales at Less Than Fair Value: Light-Walled Rectangular Pipe and Tube from Turkey,* 73 FR 19814 (April 11, 2008).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–427–830]

Strontium Chromate From France: Preliminary Results of Antidumping Duty Administrative Review; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that Société Nouvelle des Couleurs Zinciques (SNCZ) made sales of subject merchandise at less than normal value during the period of review (POR) May 17, 2019, through October 31, 2020. Interested parties are invited to comment on these preliminary results.

DATES: Applicable August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Dennis McClure, AD/CVD Operations, Office VIII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5973.

SUPPLEMENTARY INFORMATION:

Background

In accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act), Commerce is conducting an administrative review of the antidumping duty order on strontium chromate from France.[1] On May 6, 2020, in accordance with 19 CFR 251.221(c)(1)(i), we initiated the administrative review of the *Order* covering SNCZ, the only company requested for review.[2] For a complete description of the events between the initiation of this review and these preliminary results, *see* the Preliminary Decision Memorandum.[3]

Scope of the Order

The products covered by the *Order* are strontium chromate from France. The merchandise subject to review is currently classifiable in the Harmonized Tariff Schedule of the United States (HTSUS) under subheading 2841.50.9100. Subject merchandise may also enter under HTSUS subheading 3212.90.0050. For a full description of the scope of this *Order, see* the Preliminary Decision Memorandum.[4]

Methodology

Commerce conducted this review in accordance with section 751(a) of the Act. We calculated export price and constructed export price in accordance with section 772 of the Act. We calculated normal value in accordance with section 773 of the Act.

For a full description of the methodology underlying these preliminary results, *see* the Preliminary Decision Memorandum. A list of topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice. The Preliminary Decision Memorandum is a public document and is available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, the signed Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Preliminary Results of the Review

We preliminarily determine that the following weighted-average dumping margin exists for the period May 17, 2019, through October 31, 2020:

Producer and/or exporter	Weighted-average dumping margin (percent)
Société Nouvelle des Couleurs Zinciques	14.65

[1] *See Strontium Chromate from Austria and France: Antidumping Duty Orders,* 84 FR 65349 (November 27, 2019) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 511 (January 6, 2021).

[3] *See* Memorandum, ''Strontium Chromate from France: Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[4] *Id.* at ''Scope of the Order.''

Assessment Rates

Pursuant to section 751(a)(2)(A) of the Act and 19 CFR 351.212(b)(1), Commerce will determine, 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. Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this administrative review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

If SNCZ's weighted-average dumping margin is not *de minimis* (*i.e.,* less than 0.50 percent), upon completion of the final results, Commerce intends to calculate importer-specific assessment rates on the basis of the ratio of the total amount of dumping calculated for each importer's examined sales to the total entered value of those sales. Where we do not have entered values for all U.S. sales to a particular importer, we will calculate an importer-specific, per-unit assessment rate on the basis of the ratio of the total amount of dumping calculated for the importer's examined sales to the total quantity of those sales.[5] To determine whether an importer-specific, per-unit assessment rate is *de minimis,* in accordance with 19 CFR 351.106(c)(2), we also will calculate an importer-specific *ad valorem* ratio based on estimated entered values. Where either SNCZ's weighted-average dumping margin is zero or *de minimis,* or an importer-specific *ad valorem* assessment rate is zero or *de minimis,* we will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[6] For entries of subject merchandise during the POR produced by SNCZ for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate such entries at the all-others rate[7] if there is no rate for the intermediate company(ies) involved in the transaction.[8]

The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.[9]

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for SNCZ will be equal to the weighted-average dumping margin established in the final results of this review (except, if that rate is *de minimis,* then the cash deposit rate will be zero); (2) for merchandise exported by producers 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 they were reviewed; (3) if the exporter is not a firm covered in this review or the underlying LTFV investigation but the producer is, then the cash deposit rate will be the rate established for the most recently-completed segment of this proceeding for the producer of the merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 32.16 percent, the all-others rate established in the LTFV investigation.[10] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure, Public Comment, and Opportunity To Request a Hearing

We intend to disclose the calculations performed for these preliminary results of review to interested parties within five days of the date of publication of this notice in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs to Commerce no later than 30 days after the date of publication of this notice.[11] Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[12] Pursuant to 19 CFR 351.309(c)(2) and (d)(2), parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[13] Case and rebuttal briefs should be filed using ACCESS[14] and must be served on interested parties.[15] Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[16]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically-filed document must be received successfully in its entirety by ACCESS by 5 p.m. Eastern Standard Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; (3) whether any participant is a foreign national; and (4) a list of issues parties intend to discuss. Issues raised in the hearing will be limited to those raised in the respective case and rebuttal briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[17]

Final Results of Review

Unless otherwise extended, Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h)(1).

Notification to Importers

This notice serves as a preliminary 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 Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these preliminary results in accordance with

[5] *See* 19 CFR 351.212(b)(1).

[6] *See* 19 CFR 352.106(c)(2); *see also Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

[7] *See Order.*

[8] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

[9] *See* section 751(a)(2)(C) of the Act.

[10] *See Order,* 84 FR at 65350.

[11] *See* 19 CFR 351.309(c)(1)(ii).

[12] *See* 19 CFR 351.309(d)(1) and (2); *see also Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19,* 85 FR 17006, 17007 (March 26, 2020).

[13] *See* 19 CFR 351.309(c)(2) and (d)(2).

[14] *See* 19 CFR 351.303.

[15] *See* 19 CFR 351.303(f).

[16] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[17] *See* 19 CFR 351.310(c).

sections 751(a)(1) and 777(i) of the Act, and 19 CFR 351.213(h) and 351.221(b)(4).

Dated: July 27, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Discussion of the Methodology
V. Currency Conversion
VI. Recommendation

[FR Doc. 2021–16419 Filed 7–30–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–837]

Polyethylene Terephthalate Film, Sheet, and Strip From Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) is conducting an administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip (PET Film) from Taiwan. The period of review (POR) is July 1, 2019, through June 30, 2020. This review covers the following producers and exporters from Taiwan, Nan Ya Plastics Corporation (Nan Ya), Shinkong Materials Technology Corporation (SMTC)/Shinkong Synthetic Fibers Corporation (SSFC). Commerce preliminarily determines that sales of subject merchandise have not been made below normal value (NV) by Nan Ya during the POR. In addition, we preliminarily find that SMTC/SSFC had no shipments during the POR. Interested parties are invited to comment on these preliminary results.

DATES: Applicable August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Jacqueline Arrowsmith, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–5255.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2020, Commerce published in the **Federal Register** a notice of opportunity to request an administrative review of the AD order on PET film from Taiwan.[1] On July 27, 2020, Polyplex USA LLC (Polyplex USA), a domestic producer and interested party, requested a review of Nan Ya, SMTC and SSFC.[2] On July 30, 2020, the petitioners [3] requested a review of Nan Ya and SMTC.[4] Nan Ya self-requested an administrative review of its sales on July 31, 2020.[5] On September 3, 2020, in accordance with 19 CFR 351.221(c)(1)(i), Commerce published a notice of initiation of administrative review of the antidumping duty order on PET Film from Taiwan.[6] On December 2, 2020, Polyplex USA withdrew its request for an administrative review of entries of PET film for all of the companies that it requested be reviewed in this administrative review period: Nan Ya, SSFC and SMTC.[7]

On September 30, 2020, SMTC and SSFC each claimed that they did not sell or export any subject merchandise to the United States during the POR.[8] On November 24, 2020, Commerce uploaded entry data on the record of the administrative review.[9] On December 1, 2020, SMTC submitted comments explaining and documentation showing that neither SMTC nor SSFC had produced subject merchandise during the POR or three months prior to the POR.[10] No rebuttal comments were submitted. On January 7, 2021, Commerce sent a no shipment inquiry for SMTC and SSFC to U.S Customs and Border Protection (CBP).[11] On June 7, 2021, CBP replied that it found no evidence of shipments from SMTC and SSFC during the POR.[12]

On December 11, 2020, Commerce issued its initial questionnaire to Nan Ya.[13] Between January 4, 2021 and January 21, 2021,[14] Nan Ya submitted its responses to section A and sections B through D of the questionnaire. On June 16, 2021, Commerce issued a supplemental questionnaire to Nan Ya.[15] On June 30, 2021, Nan Ya submitted its supplemental questionnaire response.[16]

On March 25, 2021, in accordance with section 751(a)(3)(A) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.213(h)(2), Commerce extended the due date for the preliminary results by 60 days (from April 2, 2020, to June 2, 2021).[17] On June 1, 2021, we extended the deadline by an additional 30 days.[18] On July 2, 2021, we extended the deadline until July 30, 2021.[19]

Scope of the Order

The merchandise subject to the order is PET Film. The PET Film subject to

[1] *See Antidumping or Countervailing Duty Order, Finding or Suspended Investigation; Opportunity to Request Administrative Review,* 85 FR 39531 (July 1, 2020).

[2] *See* Polyplex USA LLC's Letter, ''Polyethylene Terephthalate ('PET') Film from Taiwan: Polyplex USA LLC's Request for AD Administrative Review,'' dated July 27, 2020.

[3] The petitioners consist of DuPont Teijin Films; Mitsubishi Polyester Film, Inc.; and SKC, Inc. (petitioners).

[4] *See* Petitioners' Letter, ''Polyethylene Terephthalate (PET) Film from Taiwan: Request for Antidumping Duty Administrative Review,'' dated July 30, 2020.

[5] *See* Nan Ya Plastics Corporation's Letter, ''Polyethylene Terephthalate (PET) Film from Taiwan,'' dated July 31, 2020.

[6] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 54983 (September 3, 2020) (*Initiation Notice*).

[7] *See* Polyplex USA LLC's Letter, ''Polyethylene Terephthalate ('PET') Film from Taiwan: Polyplex USA LLC's Withdrawal of Request for Review for Polyplex USA LLC,'' dated December 2, 2020.

[8] *See* SMTC's Letter, ''Polyethylene Terephthalate Film, Sheet and Strip from Taiwan; No Shipment Certification,'' dated September 30, 2020; *see also* SSFC's Letter, ''Polyethylene Terephthalate Film, Sheet and Strip from Taiwan; No Shipment Certification,'' dated September 30, 2020.

[9] *See* Memorandum, ''Antidumping Duty Administrative Review of Polyethylene Terephthalate Film, Sheet and Strip (PET Film) from Taiwan: U.S. Customs Entries for Shinkong Materials Technology Corporation and Shinkong Synthetic Fibers Corporation,'' dated November 24, 2020.

[10] *See* SMTC's Letter, ''Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; Comments on Entry Data,'' dated December 1, 2020.

[11] *See* Message 1008401 to CBP, dated January 8, 2021.

[12] *See* Memorandum, ''Polyethylene terephthalate film, sheet, and strip (PET Film) from Taiwan; No Shipment Inquiry for Shinkong Materials Technical Corporation and/or Shinkong Synthetic Fibers Corporation During the Period 07/01/2019 through 06/30/2020,'' dated June 7, 2021.

[13] *See* Commerce's Letter, Antidumping Duty Questionnaire, dated December 11, 2020.

[14] *See* Nan Ya's Letter, ''Polyethylene Terephthalate (PET) Film from Taiwan,'' dated January 4, 2021; *see also* Nan Ya's Letter, ''January 21, 2021 Sections B through Q Response,'' dated January 21, 2021.

[15] *See* Commerce's Letter, Antidumping Duty Questionnaire, dated June 16, 2021.

[16] *See* Nan Ya's Letter, ''June 30, 2021 Supplemental Questionnaire Response,'' dated June 30, 2021.

[17] *See* Memorandum, ''Polyethylene Terephthalate (PET) Film, Sheet and Strip from Taiwan: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review (2019–2020),'' dated March 25, 2021.

[18] *See* Memorandum ''Polyethylene Terephthalate (PET) Film, Sheet and Strip from Taiwan: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review (2019–2020),'' dated June 1, 2021.

[19] *See* Memorandum ''Polyethylene Terephthalate Film, Sheet and Strip from Taiwan: Extension of Deadline for Preliminary Results of Antidumping Duty Administrative Review (2019–2020),'' dated July 2, 2021.

the order is currently classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States. Although the HTSUS number is provided for convenience and for customs purposes, the written product description, available in the Preliminary Decision Memorandum, remains dispositive.[20]

Preliminary Determination of No Shipments

Based on U.S. Customs and Border Protection (CBP)'s response to Commerce's no shipment inquiry as well the certifications and supporting documentation provided by SMTC and SSFC in their no shipment certifications, we preliminarily determine that SMTC and SSFC[21] had no shipments of the subject merchandise during the POR. Consistent with Commerce's practice, we will not rescind the review with respect to SMTC/SSFC, but rather will complete the review and issue appropriate liquidation instructions to CBP based on the final results.[22] For additional information regarding this determination, *see* the No Shipments' Determination for SMTC and SSFC Memorandum.[23]

Methodology

Commerce is conducting this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Export price is calculated in accordance with section 772 of the Act. NV is calculated in accordance with section 773 of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. A list of topics included in the Preliminary Decision Memorandum is included as an Appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the internet at *http://enforcement.trade.gov/frn/index.html.*

Preliminary Results of Review

As a result of this review, we preliminarily determine the following weighted-average dumping margin for the period July 1, 2019, through June 30, 2020:

Producer/exporter	Weighted-average dumping margin (percent)
Nan Ya Plastics Corporation	0.00

Disclosure and Public Comment

We intend to disclose the calculations performed to parties in this proceeding within five days after public announcement of the preliminary results in accordance with 19 CFR 351.224(b). Pursuant to 19 CFR 351.309(c), interested parties may submit case briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than seven days after the date for filing case briefs.[24] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[25]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing, must submit a written request to the Acting Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS. An electronically filed document must be received successfully in its entirety by Commerce's electronic records system, ACCESS, by 5 p.m. Eastern Time within 30 days after the date of publication of this notice. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. Commerce intends to issue the final results of this administrative review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, unless extended, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon completion of this administrative review, Commerce shall determine and U.S. Customs and Border Protection (CBP) shall assess antidumping duties on all appropriate entries. If a respondent's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent) in the final results of this review, we will calculate importer-specific *ad valorem* assessment rates on the basis of the ratio of the total amount of dumping calculated for an importer's examined sales and the total entered value of such sales in accordance with 19 CFR 351.212(b)(1). Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

Commerce clarified its ''automatic assessment'' regulation on May 6, 2003.[26] This clarification applies to entries of subject merchandise during the POR produced by a respondent for which it did not know its 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.

Commerce intends to issue assessment instructions to CBP 35 days after the date of publication of the final results of this administrative review in the **Federal Register**.

Cash Deposit Requirements

The following deposit requirements will be effective for all shipments of PET Film from Taiwan entered, or withdrawn from warehouse, for

[20] A full description of the scope of the order is contained in the Preliminary Decision Memorandum, which is dated concurrently with, and hereby adopted by, this notice.

[21] In the 2011–2012 administrative review, Commerce determined that SSFC and SMTC were a single entity. *See Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; Preliminary Results of Antidumping Duty Administrative Review; 2011–2012,* 78 FR 48651 (August 9, 2013), and accompanying Preliminary Decision Memorandum, unchanged in *Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan; Final Results of Antidumping Duty Administrative Review; 2011–2012,* 79 FR 11407 (February 28, 2014). We have treated SMTC and SSFC as a single entity in all subsequent reviews and have included SSFC when only SMTC was requested in the administrative review. There is no information on the record of this administrative review that would lead Commerce to reconsider that determination. Accordingly, we continue to treat SMTC and SSFC as a single entity for purposes of this administrative review.

[22] *See Polyethylene Terephthalate Film, Sheet, and Strip from Taiwan: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2018–2019,* 85 FR 74673 (November 23, 2020), unchanged in *Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan: Final Results of Antidumping Duty Administrative Review; 2018–2019,* 86 FR 14311 (March 15, 2021).

[23] *See* Memorandum, ''No Shipments' Memorandum for Shinkong Materials Corporation (SMTC) and Shinkong Synthetic Fibers Corporation (SSFC),'' dated concurrently with this notice.

[24] *See* 19 CFR 351.309(d).

[25] *See* 19 CFR 351.303 (for general filing requirements).

[26] For a full discussion of this clarification, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003) (*Assessment Policy Notice*).

consumption on or after the date of publication of the final results of this administrative review, as provided for by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for the company under review will be the rate established in the final results of this review (except, if the rate is zero or *de minimis,* no cash deposit will be required); (2) for previously reviewed or investigated companies not listed above, the cash deposit rate will continue to be the company-specific rate published for the most recent period; (3) if the exporter is not a firm covered in this review, a prior review, or the less-than-fair-value investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recent period for the manufacturer of the merchandise; and (4) the cash deposit rate for all other manufacturers or exporters is 2.40 percent.[27] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary 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 Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213(h)(1).

Dated: July 26, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Preliminary Determination of No Shipments for SMTC/SSFC
V. Comparisons to Normal Value
VI. Date of Sale
VII. Export Price
VIII. Normal Value
IX. Currency Conversion
X. Recommendation

[FR Doc. 2021–16398 Filed 7–30–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Advance Notification of Sunset Review

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

Background

Every five years, pursuant to the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) and the International Trade Commission automatically initiate and conduct reviews to determine whether revocation of a countervailing or antidumping duty order or termination of an investigation suspended under section 704 or 734 of the Act would be likely to lead to continuation or recurrence of dumping or a countervailable subsidy (as the case may be) and of material injury.

Upcoming Sunset Reviews for September 2021

Pursuant to section 751(c) of the Act, the following Sunset Reviews are scheduled for initiation in September 2021 and will appear in that month's *Notice of Initiation of Five-Year Sunset Reviews* (Sunset Review).

	Department contact
Antidumping Duty Proceedings	
Hot-Rolled Steel Flat Products from Australia, A–602–809 (1st Review)	Jacky Arrowsmith; (202) 482–5255.
Hot-Rolled Steel Flat Products from Brazil, A–351–845 (1st Review)	Jacky Arrowsmith; (202) 482–5255.
Hot-Rolled Steel Flat Products from Japan, A–588–874 (1st Review)	Jacky Arrowsmith; (202) 482–5255.
Hot-Rolled Steel Flat Products from Netherlands, A–421–813 (1st Review)	Jacky Arrowsmith; (202) 482–5255.
Hot-Rolled Steel Flat Products from South Korea, A–580–883 (1st Review)	Jacky Arrowsmith; (202) 482–5255.
Hot-Rolled Steel Flat Products from Turkey, A–489–826 (1st Review)	Jacky Arrowsmith; (202) 482–5255.
Hot-Rolled Steel Flat Products from United Kingdom, A–412–825 (1st Review)	Jacky Arrowsmith; (202) 482–5255.
Certain Hot-Rolled Carbon Steel Flat Products from Russia, A–821–809 (4th Review)	Jacky Arrowsmith; (202) 482–5255.
Countervailing Duty Proceedings	
Hot-Rolled Steel Flat Products from Brazil, C–351–846 (1st Review)	Mary Kolberg; (202) 482–1785.
Hot-Rolled Steel Flat Products from South Korea, C–580–884 (1st Review)	Thomas Martin; (202) 482–3936.
Suspended Investigations	
Lemon Juice from Argentina, A–357–818 (2nd Review)	Jacky Arrowsmith; (202) 482–5255.

Commerce's procedures for the conduct of Sunset Review are set forth in 19 CFR 351.218. The *Notice of Initiation of Five-Year (Sunset) Review* provides further information regarding what is required of all parties to participate in Sunset Review.

Pursuant to 19 CFR 351.103(c), Commerce will maintain and make available a service list for these proceedings. To facilitate the timely preparation of the service list(s), it is requested that those seeking recognition as interested parties to a proceeding contact Commerce in writing within 10 days of the publication of the Notice of Initiation.

Please note that if Commerce receives a Notice of Intent to Participate from a member of the domestic industry within 15 days of the date of initiation, the review will continue. Thereafter, any interested party wishing to participate in the Sunset Review must provide substantive comments in response to the notice of initiation no later than 30 days after the date of initiation. Note that Commerce has modified certain of its requirements for serving documents

[27] *See Notice of Amended Final Antidumping Duty Determination of Sales at Less Than Fair Value and Antidumping Duty Order: Polyethylene Terephthalate Film, Sheet, and Strip (PET Film) from Taiwan,* 67 FR 44174 (July 1, 2002).

containing business proprietary information, until further notice.[1]

This notice is not required by statute but is published as a service to the international trading community.

Dated: July 21, 2021.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2021–16433 Filed 7–30–21; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–900]

Diamond Sawblades and Parts Thereof From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily finds that certain producers and/or exporters made sales of diamond sawblades and parts thereof (diamond sawblades) at less than normal value during the period of review (POR) November 1, 2019, through October 31, 2020. Interested parties are invited to comment on these preliminary results of review.

DATES: Applicable August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Allison Hollander, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–2805.

SUPPLEMENTARY INFORMATION:

Background

On November 4, 2009, we published in the **Federal Register** an antidumping duty order on diamond sawblades from the Peoples' Republic of China (China).[1] On November 3, 2020, we published in the **Federal Register** a notice of opportunity to request an administrative review of the *Order.*[2] On January 6, 2021, based on timely requests for an administrative review, Commerce initiated the administrative review of the antidumping duty order on diamond sawblades.[3] The administrative review covers 53 companies, which is inclusive of the two mandatory respondents, Jiangsu Fengtai Single Entity (Jiangsu Fengtai) and Zhejiang Wanli Tool Group Co., Ltd. (Zhejiang Wanli).[4]

Scope of the Order

The products covered by this *Order* are diamond sawblades. A full description of the scope of the *Order* is contained in the Preliminary Decision Memorandum.[5]

Preliminary Determination of No Shipments

Six companies that received a separate rate in previous segments of the proceeding and are subject to this review reported that they did not have any exports of subject merchandise during the POR.[6] To date, we have found no evidence calling into question the no-shipment claims made by four of these companies;[7] therefore, we preliminarily find that these four companies had no shipments of subject merchandise to the United States during the POR. For two of the six companies, because CBP data indicated entries during the POR, we requested entry documentation from CBP.[8] Based on information on the record, we preliminarily find that Husqvarna (Hebei) Co., Ltd. (Husqvarna) had entries of subject merchandise during the POR. Therefore, because it did not file a separate rate application or separate rate certification (SRC), we are preliminarily considering Husqvarna to be part of the China-wide entity. We additionally find, based on information on the record, that Weihai Xiangguang Mechanical Industrial Co., Ltd. (Weihai Xiangguang) did not have entries of subject merchandise during the POR. Therefore, we preliminarily find that Weihai Xiangguang had no shipments of subject merchandise to the United States during the POR. For additional information regarding these preliminary determinations, *see* the Preliminary Decision Memorandum.

Separate Rates

Commerce preliminarily determines that one respondent is eligible to receive a separate rate in this review.[9]

Separate Rates for Eligible Non-Selected Respondents

Consistent with our practice, because we preliminarily denied the separate rate eligibility for the two respondents selected for individual examination, Jiangsu Fengtai and Zhejiang Wanli, and treated them as part of the China-wide entity, we preliminarily applied to the non-selected respondent the separate rate assigned to eligible respondents in the last completed administrative review, which is 0.00 percent.[10]

China-Wide Entity

Under Commerce's policy regarding the conditional review of the China-wide entity,[11] the China-wide entity will not be under review unless a party specifically requests, or Commerce self-initiates, a review of the entity. Because

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[1] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[1] *See Diamond Sawblades and Parts Thereof from the People's Republic of China and the Republic of Korea: Antidumping Duty Orders,* 74 FR 57145 (November 4, 2009) (*Order*).

[2] *See Antidumping or Countervailing Duty Order, Finding, or Suspended Investigation; Opportunity To Request Administrative Review,* 85 FR 69586 (November 3, 2020).

[3] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 86 FR 511 (January 6, 2021).

[4] *See* Memorandum, ''Antidumping Duty Administrative Review of Diamond Sawblades and Parts Thereof from the People's Republic of China Administrative Review 2019–2020: Respondent Selection,'' dated March 2, 2021.

[5] *See* Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2019–2020,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

[6] *See* Bosun Tools Co., Ltd.'s Letter, ''Diamond Sawblades from the People's Republic of China—No Sales Certification,'' dated February 5, 2021; Chengdu Huifeng New Material Technology Co., Ltd.'s Letter, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Submission of Statement of No Shipments,'' dated February 4, 2021; Danyang Weiwang Tools Manufacturing Co., Ltd.'s Letter, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Submission of Statement of No Shipments,'' dated January 20, 2021; Husqvarna (Hebei) Co., Ltd.'s and Husqvarna Construction Products North America's Letter, ''Diamond Sawblades from the People's Republic of China: Notification of No Shipments,'' dated January 12, 2021; Weihai Xiangguang Mechanical Industrial Co., Ltd.'s Letter, ''No Shipment Letter for Weihai Xiangguang Mechanical Industrial Co., Ltd.: Diamond Sawblades and Parts Thereof from the People's Republic of China,'' dated February 12, 2021; and, Wuhan Wanbang Laser Diamond Tools Co., Ltd.'s Letter, ''Diamond Sawblades and Parts Thereof from the People's Republic of China: Submission of Statement of No Shipments,'' dated January 18, 2021.

[7] *See* Memorandum, ''No shipment inquiry with respect to the companies below during the period 11/01/2019 through 10/31/2020,'' dated March 25, 2021; *see also* Memorandum, ''Diamond Sawblades and Parts Thereof from the People's Republic of China; No Shipment Inquiry for Wuhan Wanbang Laser Diamond Tools Co., Ltd. during the period 11/01/2019 through 10/31/2020,'' dated May 25, 2021.

[8] *See* Memorandum, ''Notification of Receipt of U.S. Entry Documents,'' dated April 1, 2021 at Attachment 1; *see also* Commerce's Letter placing entry documentation on the record, dated June 25, 2021.

[9] *See* Preliminary Decision Memorandum at 6–7.

[10] *See* Preliminary Decision Memorandum at 7.

[11] *See Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings,* 78 FR 65963 (November 4, 2013).

no party requested a review of the China-wide entity in this review, the entity is not under review, and the entity's rate (*i.e.,* 82.05 percent) is not subject to change.[12] Aside from the no-shipment and separate rate companies discussed above, Commerce considers all other companies for which a review was requested (which did not file a separate rate application) listed in Appendix II to this notice, to be part of the China-wide entity.[13] Additionally, as discussed above, because we denied separate rate eligibility for Jiangsu Fengtai and Zhejiang Wanli, these two companies are also part of the China-wide entity.

Methodology

Commerce is conducting this review in accordance with section 751(a)(1)(B) of the Tariff Act of 1930, as amended (the Act).

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum. The Preliminary Decision Memorandum is a public document and is made available to the public via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov,* and to all parties in the Central Records Unit, Room B8024 of the main Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at *http://enforcement.trade.gov/frn/.* A list of the topics discussed in the Preliminary Decision Memorandum is attached as an appendix to this notice.

Preliminary Results of the Administrative Review

Commerce preliminarily determines that the following weighted-average dumping margin exists for the administrative review covering the period November 1, 2019, through October 31, 2020:

Exporters: Separate rate applicable to the following non-selected companies	Weighted-average dumping margin (percent)
Xiamen ZL Diamond Technology Co., Ltd	0.00

Disclosure

Normally, Commerce discloses to interested parties the calculations performed in connection with the preliminary results of a review within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of preliminary results in the **Federal Register**, in accordance with 19 CFR 351.224(b). However, because Commerce preliminarily denied the separate rate eligibility for the two respondents selected for individual examination and treated them as part of the China-wide entity, there are no calculations to disclose.

Public Comment

Pursuant to 19 CFR 351.309(c)(ii), interested parties may submit case briefs no later than 30 days after the date of publication of this notice.[14] Rebuttal briefs, limited to issues raised in the case briefs, may be filed no later than seven days after the date for filing case briefs.[15] Commerce has modified certain of its requirements for serving documents containing business proprietary information until further notice.[16] Parties who submit case briefs or rebuttal briefs in this proceeding are encouraged to submit with each argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[17]

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically using ACCESS. Requests should contain: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of issues to be discussed. Issues raised in the hearing will be limited to those raised in the respective case briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a time and date to be determined. An electronically filed document must be received successfully in its entirety by ACCESS by 5:00 p.m. Eastern Time within 30 days after the date of publication of this notice.[18]

Unless the deadline is extended, Commerce intends to issue the final results of these reviews, including the results of its analysis of the issues raised in any written briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h).

Assessment Rates

Upon issuing the final results, Commerce will determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.[19] If the preliminary results are unchanged for the final results, we will instruct CBP to apply an *ad valorem* assessment rate of 82.05 percent to all entries of subject merchandise during the POR which were exported by the companies listed in Appendix II of this notice and an *ad valorem* assessment rate of 0.00 percent to all entries of subject merchandise during the POR which were exported by the non-selected respondent eligible for a separate rate, listed above, Xiamen ZL. If Commerce 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 China-wide rate.[20]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this review for shipments of the subject merchandise from China 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 subject merchandise exported by the company listed above that has a separate rate, the

[12] *See, e.g., Diamond Sawblades and Parts Thereof from the People's Republic of China; Final Results of Antidumping Duty Administrative Review; 2012–2013,* 80 FR 32344, 32345 (June 8, 2015).

[13] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 83 FR 1329, 1331–32 (January 11, 2018) ("All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME countries must complete, as appropriate, either a separate rate application or certification, as described below."). *See* Appendix II for the list of companies that are subject to this administrative review that are considered to be part of the China-wide entity.

[14] *See* 19 CFR 351.309(c).

[15] *See* 19 CFR 351.309(d).

[16] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[17] *See* 19 CFR 351.309(c)(2) and (d)(2) and 19 CFR 351.303 (for general filing requirements).

[18] *See* 19 CFR 351.310(c).

[19] *See* 19 CFR 351.212(b)(1).

[20] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694, 65695 (October 24, 2011).

cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this administrative review (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed Chinese and non-Chinese exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the existing exporter-specific rate; (3) for all Chinese exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be that for the China-wide entity; and (4) for all non-Chinese exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the Chinese exporter that supplied that non-Chinese exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a preliminary 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 these PORs. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

Notification to Interested Parties

Commerce is issuing and publishing the preliminary results of this review in accordance with sections 751(a)(1)(B), 751(a)(3) and 777(i) of the Act, and 19 CFR 351.213 and 351.221(b)(4).

Dated: July 26, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I—List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Preliminary Determination of No Shipments
V. Discussion of the Methodology
VI. Recommendation

Appendix II

Companies that are subject to this administrative review that are considered to be part of the China-wide entity are:

ASHINE Diamond Tools Co., Ltd.
Danyang City Ou Di Ma Tools Co., Ltd.
Danyang Hantronic Import & Export Co., Ltd.
Danyang Huachang Diamond Tools Manufacturing Co., Ltd.
Danyang Like Tools Manufacturing Co., Ltd.
Danyang NYCL Tools Manufacturing Co., Ltd.
Danyang Tongyu Tools Co., Ltd.
Danyang Tsunda Diamond Tools Co., Ltd.
Diamond Tools Technology (Thailand) Co., Ltd.
Fujian Quanzhou Aotu Precise Machine Co., Ltd.
Guilin Tebon Superhard Material Co., Ltd.
Hangzhou Deer King Industrial and Trading Co., Ltd.
Hangzhou Kingburg Import & Export Co., Ltd.
Hebei XMF Tools Group Co., Ltd.
Henan Huanghe Whirlwind Co., Ltd.
Henan Huanghe Whirlwind International Co., Ltd.
Hong Kong Hao Xin International Group Limited
Hubei Changjiang Precision Engineering Materials Technology Co., Ltd.
Hubei Sheng Bai Rui Diamond Tools Co., Ltd.
Husqvarna (Hebei) Co., Ltd.
Huzhou Gu's Import & Export Co., Ltd.
Jiangsu Fengtai Single Entity *
Jiangsu Huachang Diamond Tools Manufacturing Co., Ltd.
Jiangsu Inter-China Group Corporation
Jiangsu Yaofeng Tools Co., Ltd.
Jiangsu Youhe Tool Manufacturer Co., Ltd.
Orient Gain International Limited
Pantos Logistics (HK) Company Limited
Protec Tools Co., Ltd.
Pujiang Talent Diamond Tools Co., Ltd.
Qingdao Hyosung Diamond Tools Co., Ltd.
Qingdao Shinhan Diamond Industrial Co., Ltd.
Qingyuan Shangtai Diamond Tools Co., Ltd.
Quanzhou Sunny Superhard Tools Co., Ltd.
Quanzhou Zhongzhi Diamond Tool Co., Ltd.
Rizhao Hein Saw Co., Ltd.
Saint-Gobain Abrasives (Shanghai) Co., Ltd.
Shanghai Jingquan Industrial Trade Co., Ltd.
Shanghai Starcraft Tools Co. Ltd.
Shanghai Vinon Tools Industrial Co.
Sino Tools Co., Ltd.
Wuhan Baiyi Diamond Tools Co., Ltd.
Wuhan Sadia Trading Co., Ltd.
Wuhan ZhaoHua Technology Co., Ltd.
Zhejiang Wanli Tool Group Co., Ltd. *
ZL Diamond Technology Co., Ltd.
ZL Diamond Tools Co., Ltd.

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* Selected as mandatory respondents, these companies were found to be part of the China-wide entity in the instant review.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–847]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes From Mexico: Final Results of Antidumping Duty Administrative Review; 2018–2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) finds that the producers/exporters subject to this administrative review did not make sales of subject merchandise at less than normal value during the period of review (POR) September 1, 2018, through August 31, 2019.

DATES: Applicable August 2, 2021.

FOR FURTHER INFORMATION CONTACT: David Goldberger or David Crespo, AD/CVD Operations, Office II, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–4136 or (202) 482–3693, respectively.

SUPPLEMENTARY INFORMATION:

Background

This review covers 11 producers/exporters of the subject merchandise. Commerce selected two companies, Maquilacero S.A. de C.V. (Maquilacero) and Productos Laminados de Monterrey S.A. de C.V. (Prolamsa) (collectively, the mandatory respondents), for individual examination. The producers/exporters not selected for individual examination are listed in Appendix II.

On January 26, 2021, Commerce published the *Preliminary Results.*[1] We invited interested parties to comment on the *Preliminary Results.*[2] On March 8, 2021, Nucor Tubular Products Inc. (*i.e.,* the domestic interested party) and Maquilacero filed case briefs. On March 17, 2021, the domestic interested party, Maquilacero, and Prolamsa filed rebuttal briefs. On April 8, 2021, we postponed the final results until July 23, 2021.[3] For a description of the events that occurred since the *Preliminary*

[1] *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico: Preliminary Results of Antidumping Duty Administrative Review; 2018–2019,* 86 FR 7067 (January 26, 2021) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *Id.*

[3] *See* Memorandum, ''Extension of Deadline for the Final Results of the 2018–2019 Antidumping Duty Administrative Review,'' dated April 8, 2021.

Results, see the Issues and Decision Memorandum.[4]

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order

The products covered by the order are heavy walled rectangular welded steel pipes and tubes from Mexico.[5] Products subject to the order are currently classified under the Harmonized Tariff Schedule of the United States (HTSUS) item number 7306.61.1000. Subject merchandise may also be classified under 7306.61.3000. Although the HTSUS numbers and ASTM specification are provided for convenience and for customs purposes, the written product description remains dispositive.

Analysis of the Comments Received

All issues raised in the case and rebuttal briefs are listed in Appendix I to this notice and addressed in the Issues and Decision Memorandum. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties regarding our *Preliminary Results,* we made certain changes to the weighted-average dumping margin calculations for Maquilacero and Prolamsa, and the companies not selected for individual review, for the final results.[6]

Final Results of the Review

We are assigning the following weighted-average dumping margins to the firms listed below for the period September 1, 2018, through August 31, 2019:

Producers/exporters	Weighted-average dumping margin (percent)
Maquilacero S.A. de C.V	0.00
Productos Laminados de Monterrey S.A. de C.V	0.00
Companies Not Selected for Individual Review[7]	0.00

Review-Specific Rate for Companies Not Selected for Individual Review

The dumping margins for the exporters or producers not selected for individual review are listed in Appendix II.

Disclosure

Commerce intends to disclose the calculations performed in connection with these final results to interested parties within five days of the date of publication of this notice, in accordance with 19 CFR 351.224(b).

Assessment Rates

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce 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.

Pursuant to 19 CFR 351.212(b)(1), where Maquilacero and Prolamsa reported the entered value of their U.S. sales, we calculated importer-specific *ad valorem* duty assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales for which entered value was reported. Where Prolamsa did not report entered value, we calculated the entered value in order to determine the assessment rate. Where either the respondent's weighted-average dumping margin is zero or *de minimis* within the meaning of 19 CFR 351.106(c)(1), or an importer-specific rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. For the companies which were not selected for individual review, because we are assigning these companies an assessment rate based on the cash deposit rate calculated for Maquilacero and Prolamsa,[8] we will instruct CBP to liquidate these entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review.[9]

Commerce's ''automatic assessment'' practice will apply to entries of subject merchandise during the POR produced by Maquilacero or Prolamsa for which the reviewed companies did not know that the merchandise they sold to the intermediary (*e.g.,* a reseller, trading company, or exporter) 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.[10]

We intend to issue liquidation instructions to CBP no earlier than 41 days after the date of publication of the final results of this review in the **Federal Register**, in accordance with 19 CFR 356.8(a).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) The cash deposit rate for each specific company listed above will be equal to the weighted-average dumping margin that is established in the final results of this review, except if the rate is less than 0.50 percent and, therefore, *de minimis* within the meaning of 19 CFR 351.106(c)(1), in which case the cash deposit rate will be zero; (2) for previously reviewed or investigated companies not covered in this review, the cash deposit will continue to be the company-specific cash deposit rate published for the most recently completed segment in which the company was reviewed; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV)

[4] *See* Memorandum, ''Issues and Decision Memorandum for the Antidumping Duty Administrative Review: Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Mexico; 2018–2019,'' dated concurrently with, and hereby adopted by, this notice (Issues and Decision Memorandum).

[5] For a full description of the scope of the order, *see* Issues and Decision Memorandum.

[6] *See* Issues and Decision Memorandum.

[7] Under section 735(c)(5)(A) of the Act, the all-others rate is normally ''an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually examined, excluding any margins that are zero or *de minimis* margins, and any margins determined entirely {on the basis of facts available}.'' For these final results, we have calculated weighted-average dumping margins for Maquilacero and Prolamsa that are zero, and we have not calculated any margins which are not zero, *de minimis,* or determined entirely on the basis of facts available. Accordingly, we have assigned to the companies not individually examined a margin of zero percent. The exporters/producers subject to this review, but not selected for individual review, are listed in Appendix II.

[8] This rate was calculated as discussed in footnote 7, above.

[9] *See* section 751(a)(2)(C) of the Act.

[10] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

investigation, but the producer is, then the cash deposit rate will be the cash deposit rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other producers or exporters will continue to be 4.91 percent, the all-others rate established in the LTFV investigation.[11] 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 Commerce'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 disposition 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 return/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.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5).

Dated: July 22, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix I

List of Topics Discussed in the Issues and Decision Memorandum

I. Summary
II. Background
III. Scope of the Order
IV. Margin Calculations
V. Discussion of the Issues

General Issues

Comment 1: Deduction of 232 Duties

Issues Related to Maquilacero

Comment 2: Alleged Error in Calculating Quarterly Cost of Hot-rolled Coil (HRC)
Comment 3: Adjustment to Costs for Non-Prime Products
Comment 4: Adjustment to Maquilacero's Scrap Offset

Issues Related to Prolamsa

Comment 5: Home Market Level of Trade (LOT) and Constructed Export Price (CEP) Offset
Comment 6: Overrun Sales Outside the Ordinary Course of Trade
Comment 7: Errors in the Application of U.S. Freight Revenue
Comment 8: Claimed Inventory Adjustment to Raw Material Costs
Comment 9: Error in Standard Cost Adjustment
Comment 10: Change in Average Useful Life (AUL) of Certain Assets
Comment 11: Calculation of General and Administrative (G&A) Expense Ratio
Comment 12: Adjustment to Prolamsa's Scrap Offset

VI. Recommendation

Appendix II

Review-Specific Rate Applicable to Companies Not Selected for Individual Review:[12]

Exporter or producer	Weighted-average dumping margin (percent)
Arco Metal S.A. de C.V	0.00
Forza Steel S.A. de C.V	0.00
Industrias Monterrey, S.A. de C.V	0.00
Perfiles y Herrajes LM S.A. de C.V	0.00
PYTCO S.A. de C.V	0.00
Regiomontana de Perfiles y Tubos S.A. de C.V	0.00
Ternium S.A. de C.V	0.00
Tuberia Nacional, S.A. de C.V	0.00
Tuberias Procarsa S.A. de C.V	0.00

[FR Doc. 2021–16396 Filed 7–30–21; 8:45 am]

BILLING CODE 3510–DS–P

[11] *See Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from the Republic of Korea, Mexico, and the Republic of Turkey: Antidumping Duty Orders,* 81 FR 62865, 62866 (September 13, 2016).

[12] For these final results, we have calculated weighted-average dumping margins for Maquilacero and Prolamsa that are zero, and we have not calculated any margins which are not zero, *de minimis,* or determined entirely on the basis of facts available. Accordingly, we have assigned to the companies not individually examined a margin of zero percent. *See* section 735(c)(5)(A) of the Act.

DEPARTMENT OF COMMERCE

International Trade Administration

[C–533–825]

Polyethylene Terephthalate Film, Sheet, and Strip From India: Preliminary Results of Countervailing Duty Administrative Review, Rescission in Part, and Intent To Rescind in Part; 2019

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Commerce) preliminarily determines that countervailable subsidies are being provided to SRF Limited/SRF Limited of India (SRF), a producer and exporter of polyethylene terephthalate film, sheet, and strip (PET film) from India. The period of review is January 1, 2019, through December 31, 2019. Interested parties are invited to comment on these preliminary results.

DATES: Applicable August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Nicholas Czajkowski or Konrad Ptaszynski, AD/CVD Operations, Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1395 or (202) 482–6187, respectively.

SUPPLEMENTARY INFORMATION:

Background

On July 1, 2002, Commerce published in the **Federal Register** the countervailing duty (CVD) order on PET film from India.[1] On September 3, 2020, Commerce published a notice of initiation of an administrative review of the *Order.*[2] On February 25, 2021, Commerce extended the deadline for the preliminary results of this review to no later than July 30, 2021.[3] For a complete description of the events that followed the initiation of this review, *see* the Preliminary Decision Memorandum.[4]

[1] *See Countervailing Duty Order; Polyethylene Terephthalate Film Sheet, and Strip (PET Film) from India,* 67 FR 44179 (July 1, 2002) (*Order*).

[2] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 85 FR 54983 (September 3, 2020).

[3] *See* Memorandum, ''Polyethylene Terephthalate Film, Sheet and Strip from India: Extension of Deadline for Preliminary Results of Countervailing Duty Administrative Review; 2019,'' dated February 25, 2021.

[4] *See* Memorandum, ''Decision Memorandum for the Preliminary Results, Partial Rescission and Intent to Rescind in Part of the Countervailing Duty Administrative Review: Polyethylene Terephthalate Film, Sheet, and Strip from India; 2019,'' dated concurrently with, and hereby adopted by, this notice (Preliminary Decision Memorandum).

Scope of the Order

The products covered by this *Order* are PET film from India. For a complete description of the scope of the *Order, see* the Preliminary Decision Memorandum.[5]

Rescission of Administrative Review, in Part

Pursuant to 19 CFR 351.213(d)(1), Commerce will rescind an administrative review, in whole or in part, if the parties that requested a review withdraw the request within 90 days of the date of publication of the notice of initiation. Commerce received timely-filed withdrawal requests from to MTZ Polyesters Ltd. (MTZ), Polyplex Corporation Ltd. (Polyplex), and Uflex Ltd. (Uflex), pursuant to 19 CFR 351.213(d)(1). Because the withdrawal requests were timely filed, and no other party requested a review of these companies, in accordance with 19 CFR 351.213(d)(1), Commerce is rescinding this review of the *Order* with respect to MTZ, Polyplex, Uflex.

Intent To Rescind Administrative Review, in Part

It is Commerce's practice to rescind an administrative review of a CVD order, pursuant to 19 CFR 351.213(d)(3), when there are no reviewable entries of subject merchandise during the POR for which liquidation is suspended.[6] Normally, upon completion of an administrative review, the suspended entries are liquidated at the CVD assessment rate calculated for the review period.[7] Therefore, for an administrative review of a company to be conducted, there must be a reviewable, suspended entry that Commerce can instruct U.S. Customs and Border Protection (CBP) to liquidate at the calculated CVD assessment rate calculated for the review period.[8]

According to the CBP import data, except for the mandatory respondent and its cross-owned companies, the companies subject to this review did not have reviewable entries of subject merchandise during the POR for which liquidation is suspended. Accordingly, in the absence of reviewable, suspended entries of subject merchandise during the POR, we intend to rescind this administrative review with respect to one company, Vacmet India Ltd., in accordance with 19 CFR 351.213(d)(3).

Methodology

Commerce is conducting this administrative review in accordance with section 751(a)(1)(A) of the Tariff Act of 1930, as amended (the Act). For each of the subsidy programs found to be countervailable, we preliminarily find that there is a subsidy, *i.e.,* a financial contribution by an ''authority'' that gives rise to a benefit to the recipient, and that the subsidy is specific.[9] For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum.

A list of topics discussed in the Preliminary Decision Memorandum is included at the appendix to this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *http://access.trade.gov.* In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.*

Preliminary Rate for Non-Selected Companies Under Review

There are three companies for which a review was requested and not rescinded, and which were not selected as mandatory respondents. The statute and Commerce's regulations do not directly address the establishment of rates to be applied to companies not selected for individual examination where Commerce limits its examination in an administrative review pursuant to section 777A(e)(2) of the Act. However, Commerce normally determines the rates for non-selected companies in reviews in a manner that is consistent with section 705(c)(5) of the Act, which provides the basis for calculating the all-others rate in an investigation.

Section 705(c)(5)(A)(i) of the Act instructs Commerce, as a general rule, to calculate an all-others rate equal to the weighted average of the countervailable subsidy rates established for exporters and/or producers individually examined, excluding any rates that are zero, *de minimis,* or based entirely on facts available. In this review, none of the rates for respondents were zero, *de minimis,* or based entirely on facts available. For the companies for which a review was requested that were not selected as mandatory company respondents, and for which Commerce did not receive a timely request for withdrawal of review, Commerce based the subsidy rate on the rate calculated for the sole mandatory respondent.

Preliminary Results of Review

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily determine the following net countervailable subsidy rates for the POR:

Manufacturer/exporter	Subsidy rate (percent *ad valorem*)
SRF Limited[10]	2.82
Review-Specific Average Rate Applicable to the Following Companies[11]	
Ester Industries Limited	2.82
Garware Polyester Ltd	2.82
Jindal Polyester Ltd	2.82

Disclosure and Public Comment

We will disclose to parties in this review the calculations performed in reaching the preliminary results within five days of publication of these preliminary results.[12] Interested parties may submit written comments (case briefs) on the preliminary results no later than 30 days from the date of publication of this **Federal Register** notice, and rebuttal comments (rebuttal briefs) within seven days after the time limit for filing case briefs.[13] Pursuant to 19 CFR 351.309(d)(2), rebuttal briefs must be limited to issues raised in the case briefs. Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities.[14] All briefs must be filed electronically using ACCESS.

Pursuant to 19 CFR 351.310(c), interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, filed electronically via ACCESS by 5 p.m. Eastern Time within 30 days after the date of publication of this notice. Hearing requests should contain: (1) The party's name, address,

[5] *Id.*

[6] *See, e.g., Lightweight Thermal Paper from the People's Republic of China: Notice of Rescission of Countervailing Duty Administrative Review; 2015,* 82 FR 14349 (March 20, 2017); *see also Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Rescission of Countervailing Duty Administrative Review; 2017,* 84 FR 14650 (April 11, 2019).

[7] *See* 19 CFR 351.212(b)(2).

[8] *See* 19 CFR 351.213(d)(3).

[9] *See* sections 771(5)(B) and (D) of the Act regarding financial contribution; section 771(5)(E) of the Act regarding benefit; and section 771(5A) of the Act regarding specificity.

[10] SRF Limited is also known as SRF Limited of India.

[11] This rate is based on the rates for the respondents that were selected for individual review, excluding rates that are zero, *de minimis,* or based entirely on facts available. *See* section 735(c)(5)(A) of the Act.

[12] *See* 19 CFR 351.224(b).

[13] *See* 19 CFR 351.309(c)(1)(ii); 351.309(d)(1); and 19 CFR 351.303 (for general filing requirements).

[14] *See* 19 CFR 351.309(c)(2) and (d)(2).

and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Issues addressed at the hearing will be limited to those raised in the briefs. If a request for a hearing is made, Commerce intends to hold the hearing at a date and time to be determined.[15]

Parties are reminded that briefs and hearing requests are to be filed electronically using ACCESS and that electronically filed documents must be received successfully in their entirety by 5 p.m. Eastern Time on the due date. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business proprietary information, until further notice.[16]

Commerce intends to issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their briefs, no later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act and 19 CFR 351.213(h), unless this deadline is extended.

Assessment Rates

In accordance with 19 CFR 351.221(b)(4)(i), we preliminarily assigned subsidy rates in the amounts shown above for the producers/exporters shown above. Upon completion of the administrative review, consistent with section 751(a)(1) of the Act and 19 CFR 351.212(b)(2), Commerce shall determine, CBP shall assess, countervailing duties on all appropriate entries covered by this review. For the companies for which this review is rescinded, Commerce will instruct CBP to assess countervailing duties on all appropriate entries at a rate equal to the cash deposit of estimated countervailing duties required at the time of entry, or withdrawal from warehouse, for consumption, during the period January 1, 2019, through December 31, 2019, in accordance with 19 CFR 351.212(c)(l)(i). For the companies remaining in the review, Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S. Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

[15] *See* 19 CFR 351.310(c).

[16] *Id.*

Cash Deposit Requirements

In accordance with section 751(a)(2)(C) of the Act, Commerce intends, upon publication of the final results, to instruct CBP to collect cash deposits of estimated countervailing duties in the amounts shown for each of the respondents listed above on shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this administrative review. For all non-reviewed firms, Commerce will instruct CBP to continue to collect cash deposits of estimated countervailing duties at the most recent company-specific or all-others rate applicable to the company, as appropriate. These cash deposit instructions, when imposed, shall remain in effect until further notice.

Notification to Interested Parties

These preliminary results and notice are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(4).

Dated: July 27, 2021.

Christian Marsh,

Acting Assistant Secretary for Enforcement and Compliance.

Appendix

List of Topics Discussed in the Preliminary Decision Memorandum

I. Summary
II. Background
III. Partial Rescission of Administrative Review
IV. Non-Selected Rate
V. Intent to Rescind Administrative Review, in Part
VI. Scope of the Order
VII. Subsidies Valuation Information
VIII. Analysis of Programs
IX. Recommendation

[FR Doc. 2021–16420 Filed 7–30–21; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XB287]

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Subcommittee of the Scientific and Statistical Committee (SSC) will hold an online meeting to review new groundfish stock assessments.

DATES: The online meeting will be held Tuesday, August 17, 2021, from 8:30 a.m. to 5 p.m., Pacific Daylight Time.

ADDRESSES: This meeting will be held online. Specific meeting information, including directions on how to join the meeting and system requirements will be provided in the meeting announcement on the Pacific Council's website (see *www.pcouncil.org*). You may send an email to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov*) or contact him at (503) 820–2412 for technical assistance.

Council address: Pacific Fishery Management Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220–1384.

FOR FURTHER INFORMATION CONTACT: John DeVore, Staff Officer, Pacific Council; telephone: (503) 820–2413.

SUPPLEMENTARY INFORMATION: The SSC's Groundfish Subcommittee will review further analyses for new assessments of copper rockfish in California south of Pt. Conception, copper rockfish in California north of Pt. Conception, quillback rockfish in California, squarespot rockfish in California, and spiny dogfish as requested by the Pacific Council at their June 2021 meeting. The Groundfish Subcommittee will also review new assessments and stock assessment review reports for lingcod, and vermilion and sunset rockfishes, as well as updated catch-only projections for canary rockfish, petrale sole, darkblotched rockfish, and arrowtooth flounder. Further, the Groundfish Subcommittee will review a catch report for yelloweye rockfish to determine the adequacy of rebuilding progress. The Groundfish Subcommittee will prepare their recommendations for SSC and Pacific Council consideration at their online meetings in September. Assessment recommendations may include endorsing these new assessments for management use or requesting further analyses to be reviewed at the late September review panel (this process is outlined in the Pacific Council's Terms of Reference for the Groundfish and Coastal Pelagic Species Stock Assessment Review Process for 2021–22).

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section

305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt (*kris.kleinschmidt@noaa.gov;* (503) 820–2412) at least 10 days prior to the meeting date.

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

Dated: July 28, 2021.

Tracey L. Thompson,

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

[FR Doc. 2021–16427 Filed 7–30–21; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Public Interface Control Working Group for the NAVSTAR GPS Public Documents

AGENCY: Global Positioning System (GPS), Department of the Air Force, Department of Defense.

ACTION: Meeting notice.

SUMMARY: The Department of the Air Force is publishing this notice to announce the Space and Missile Systems Center, Portfolio Architect Corp will host the 2021 Public Interface Control Working Group and Open Public Forum to update the public on GPS public document revisions and collect issues/comments for analysis and possible integration into future GPS public document revisions.

DATES: Open to the public in person and virtually Wednesday, September 29, 2021 from 8:30 a.m. to 4:00 p.m. and Tuesday, November 19, 2019, from 8:00 a.m. to 4:00 p.m. (Pacific Time).

ADDRESSES: This meeting will be held in person at Los Angeles AFB, Great Room,-PCT Campus, 100 Sepulveda, Blvd., El Segundo, CA 90245 and virtually accessed here: *https://saicwebconferencing.zoomgov.com/j/1609131495?pwd=WTNkK01ES0pCc2NqR1VJdjhkd3NEQT09* and/or *https://conference-okc.apps.mil/webconf/2021PublicICWG* Primary Dial In: 571–200–1700, Meeting ID: 160 913 1495, Password: 813441 and Backup Dial In: 410–874–6300, Conference PIN: 961616381.

FOR FURTHER INFORMATION CONTACT: Lt. Adam Barnette, (310) 653–9518 (Voice), *SMCGPER@us.af.mil* (Email), SMC/ZACS, 483 North Aviation Blvd., El Segundo, CA 90245–2807.

SUPPLEMENTARY INFORMATION: Any member of the public wishing to provide comments may submit them to the Space & Missile Systems Center, GPS Requirements Section at *SMCGPER@us.af.mil* by August 24, 2021. Special topics may also be considered for the Public Open Forum. If you wish to present a special topic, please submit any materials to SMC/ZACS–PNT no later than August 18th, 2021. Comments will be collected, cataloged, and discussed as potential inclusions to the version following the current release. If accepted, these changes will be processed through the formal change management process for IS–GPS–200, IS–GPS–705, and IS–GPS–800. All comments must be submitted in a Comments Resolution Matrix. This form along with proposed document revisions of the documents and the official meeting notice are posted at: *https://www.gps.gov/technical/icwg/meetings/2021.* Please register for this event by emailing *SMCGPER@us.af.mil,* providing your name, organization, telephone number, email address, and country of citizenship, as well as desired mode of attendance (in-person or virtual). Attendees are highly encouraged to participate virtually. Facility capacity may be reduced based on government restrictions; in-person attendees should plan accordingly. Attendees will be expected to comply with COVID–19 health precautions in place on the date of the meeting, which are subject to change (*e.g.* social distancing and wearing a facemask). Backup dial-in & screen share website will only be used in case of primary system technical difficulties.

Adriane Paris,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2021–16360 Filed 7–30–21; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent To Grant an Exclusive Patent License

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant an exclusive patent license agreement to Palladium Labs, a C-Corporation, having a place of business at 126 Thomas Street NW, Washington, DC 20001.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to Matthew O'Brien, RDOX, Technology Transfer Office, Directed Energy Directorate, 3550 Aberdeen Avenue, Kirtland AFB, New Mexico 87117–5776; Telephone: 505–846–5028; Email: *matthew.obrien.27@us.af.mil.* Include Docket No. PRS283 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Shannon Carr, RDOX, Technology Transfer Office, Directed Energy Directorate, 3550 Aberdeen Avenue, Kirtland AFB, New Mexico 87117–5776; Telephone: 505–321–3542; Email: *shannon.carr.3.ctr@us.af.mil.*

SUPPLEMENTARY INFORMATION: The Department of the Air Force intends to grant the exclusive patent license agreement for the invention described in: U.S. 10,715,615, entitled ''Dynamic Content Distribution System and Associated Methods,'' issued 14 July 2020.

The Department of the Air Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Adriane Paris,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2021–16351 Filed 7–30–21; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Report on the Value and Effectiveness of Emergency Alternative Arrangements for the Interim Beddown of the F–22 Formal Training Unit at Eglin Air Force Base, Florida

ACTION: Notice.

SUMMARY: On June 17, 2021, the Air Force submitted a report to the Council on Environmental Quality (CEQ) that addressed the value and effectiveness of

the emergency alternative arrangements for National Environmental Policy Act (NEPA) environmental review of proposed emergency response actions agreed to by the CEQ for the Department of the Air Force's (Air Force) Interim Beddown of the F–22 Formal Training Unit at Eglin Air Force Base, Florida.

ADDRESSES: Mr. Mike Spaits, Public Affairs, 96 TW/PA, 101 West D Ave., Building 1, Suite 238, Eglin AFB, FL 32542, (850) 882–7660; *michael.spaits@us.af.mil.*

SUPPLEMENTARY INFORMATION: On December 21, 2018, the Air Force sought CEQ approval of alternative arrangements, pursuant to 40 CFR 1506.11 for implementing the procedural provisions of the NEPA, §§ 42 U.S.C. 4321, *et seq.,* to respond to a pilot manning crisis that presented significant national security implications. The emergency was the Air Force's need to restore training of replacement pilots for the F–22 in northwest Florida by January 31, 2019, and there was insufficient time to prepare an Environmental Impact Statement (EIS). The CEQ regulations implementing the procedural provisions of NEPA provide that when such emergency circumstances make it necessary for an agency to take an action without observing the normal procedures set forth in those regulations, the federal agency should consult with CEQ about alternative arrangements for compliance with NEPA. On December 21, 2018, CEQ concluded consultation and approved alternative arrangements pursuant to 40 CFR 1506.11. The Air Force immediately accepted the alternative arrangements, documenting this acceptance in a decision memorandum. On January 11, 2019, the Air Force announced its decision in the **Federal Register** (**Federal Register**, Vol. 84, No. 8, p. 103, January 11, 2019) to accept alternative arrangements approved by the CEQ. The Air Force's decision memorandum provides, ''At the conclusion of the alternative arrangements and no later than two years from the date of the Notice of Intent (NOI) to prepare an EIS, the Air Force will provide a report to CEQ on the use of the alternative arrangements that reviews the value and effectiveness of these arrangements.'' Now, at the conclusion of the alternative arrangements and approximately two years from the date of the NOI to prepare an EIS (**Federal Register** Vol 84, No. 58, p. 11289, March 26, 2019), the Air Force has prepared the required report on the use of the alternative arrangements that reviews their value and effectiveness. Additionally, as required in the alternative arrangements, the Air Force is providing this notice of the report in the **Federal Register**, local newspapers, including the Northwest Florida Daily News and the Bay Beacon, and online at *https://www.eglin.af.mil/.*

Adriane Paris,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2021–16392 Filed 7–30–21; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF DEFENSE

Department of the Air Force

Notice of Intent to Grant an Exclusive Patent License

AGENCY: Department of the Air Force, Department of Defense.

ACTION: Notice of intent.

SUMMARY: Pursuant to the Bayh-Dole Act and implementing regulations, the Department of the Air Force hereby gives notice of its intent to grant an exclusive patent license to mPower, Inc., a woman-owned small business and energy supplier, having a place of business at 5901 Indian School Rd NE, Albuquerque, NM 87110.

DATES: Written objections must be filed no later than fifteen (15) calendar days after the date of publication of this Notice.

ADDRESSES: Submit written objections to Matthew O'Brien, RDOX, Technology Transfer Office, Directed Energy Directorate, 3550 Aberdeen Avenue, Kirtland AFB, New Mexico 87117–5776; Telephone: 505–846–5028; Email: *matthew.obrien.27@us.af.mil.* Include Docket No. PRS180 in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Shannon Carr, RDOX, Technology Transfer Office, Directed Energy Directorate, 3550 Aberdeen Avenue, Kirtland AFB, New Mexico 87117–5776; Telephone: 505–321–3542; Email: *shannon.carr.3.ctr@us.af.mil.*

SUPPLEMENTARY INFORMATION: The Department of the Air Force intends to grant the exclusive patent license agreement for the invention described in: U.S. Patent No. 8,974,899, entitled ''Pseudomorphic Glass for Space Solar Cells,'' issued 10 March, 2015.

The Department of the Air Force may grant the prospective license unless a timely objection is received that sufficiently shows the grant of the license would be inconsistent with the Bayh-Dole Act or implementing regulations. A competing application for a patent license agreement, completed in compliance with 37 CFR 404.8 and received by the Air Force within the period for timely objections, will be treated as an objection and may be considered as an alternative to the proposed license.

Adriane Paris,

Acting Air Force Federal Register Liaison Officer.

[FR Doc. 2021–16349 Filed 7–30–21; 8:45 am]

BILLING CODE 5001–10–P

DEPARTMENT OF EDUCATION

Notice Inviting Applications for Funds Under the Higher Education Emergency Relief Fund (HEERF), Section 2003 of the American Rescue Plan (ARP) for Institutions of Higher Education That Meet the Criteria for the Minority Serving Institutions (MSIs) Program

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary is announcing the availability of new HEERF funding for the ARP (a)(2) grant program authorized under ARP section 2003(2) and inviting applications under Assistance Listing Number (ALN)84.425L from eligible public and private nonprofit IHEs to address needs directly related to the coronavirus. These awards are in addition to the ARP (a)(1) grants and have been allocated by the Secretary proportionally to funding for MSI programs in the Further Consolidated Appropriations Act, 2020. The institutions eligible for this funding include institutions that generally would be eligible to apply for the following grant programs under the Higher Education Act of 1965, as amended (HEA), and that are listed on the ARP (a)(2) MSI Allocation Table: Title V, part A Developing Hispanic Serving Institutions, Title V, part B Promoting Postbaccalaureate Opportunities for Hispanic Americans, and the following Title III Part A programs: Strengthening Asian American and Native American Pacific Islander-Serving Institutions (AANAPISI), Strengthening Alaska Native and Native Hawaiian-Serving Institutions (ANNH), Strengthening Native American-Serving Nontribal Institutions (NASNTI), and Strengthening Predominantly Black Institutions (PBI). This notice relates to the approved information collection

under OMB control number 1840–XXXX.

DATES:

Applications Available: August 2, 2021.

Deadline for Transmittal of Applications: Applications will be accepted on a rolling basis until October 1, 2021.

ADDRESSES: For the addresses to obtain and submit an application, please refer to the Common Instructions for Applicants to the Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *https://www.federalregister.gov/documents/2019/02/13/2019-02206/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.*

FOR FURTHER INFORMATION CONTACT: Karen Epps, U.S. Department of Education, 400 Maryland Avenue SW, Room 250–64, Washington, DC 20202. Department of Education HEERF Customer Care Center Phone: (202) 377–3711. Email: *HEERF@ed.gov.* Please also visit the HEERF III website at: *https://www2.ed.gov/about/offices/list/ope/arp.html.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

Background: On March 11, 2021, the President signed the ARP into law (Pub. L. 117–2). This law makes available approximately $39.6 billion for IHEs under HEERF, with funding appropriated through existing programs authorized under the CRRSAA.

With this notice, the Secretary is announcing the availability of HEERF grant funds under the ARP (a)(2) MSI program (ALN 84.425L).

Eligible institutions are IHEs, as defined in sections 101 and 102(c) of the HEA, 20 U.S.C. 1001 and 1002(c). Allocations for eligible IHEs will be calculated according to the formulas found in ARP section 2003(2) and section 314(a)(2) of the CRRSAA. Under ARP section 2003, grant awards under this program may be used to (1) defray expenses associated with the coronavirus, including lost revenue, reimbursement for expenses already incurred, technology costs associated with a transition to distance education, faculty and staff training, and payroll; and (2) provide financial aid grants to students (including students exclusively enrolled in distance education), which may be used for any component of the student's cost of attendance or for emergency costs that arise due to the coronavirus, such as tuition, food, housing, health care, mental health care, or childcare. In making financial aid grants to students, an IHE must prioritize grants to students with exceptional need, such as Pell recipient students. IHEs are urged to devote the maximum amount of funds possible to student financial aid grants.

Additionally, under ARP section 2003(5), institutions must use a portion of their funds under ALN 84.425L to (1) implement evidence-based practices to monitor and suppress coronavirus in accordance with the public health guidelines; and (2) conduct direct outreach to financial aid applicants about the opportunity to receive a financial aid adjustment due to recent unemployment status or other changes in financial circumstances as described in section 479A of the HEA (20 U.S.C. 1087tt).

The Department is not requiring IHEs that received grants under section 314(a)(2) of the CRRSAA to submit a new or revised application to receive funding under the ARP (a)(2) MSI program. As a result, the Department will award supplemental funds to eligible IHEs that received a section 314(a)(2) award under the CRRSAA, ALN 84.425L (identified by a Grant Award beginning with P425Lxx). No action is required by eligible IHEs to receive these supplemental awards. The project director identified on the most current Grant Award Notification (GAN) will automatically receive an email indicating a supplemental award has been made to your institution. Please note that drawing down any amount of these supplemental funds constitutes an institution's acceptance of the new ARP terms and conditions and a new Supplemental Agreement, which are attached to this notice for reference.

IHEs that have not yet complied with the reporting requirements of the HEERF grant program may receive delayed supplemental ARP (a)(2) awards and/or may receive awards with a restriction on the ability to draw down those awarded funds (route payment status) until the institution has satisfied its HEERF reporting obligations.

IHEs that did not receive a CRRSAA section 314(a)(2) MSI award but that are on the Department's section 2003(2) ARP MSI Allocation Table may apply for and receive an ARP (a)(2) MSI grant award. The Department must receive an application from such institutions within 60 days of the publication of this notice.

Program Authority: Section 2003 of the ARP and section 314 of the CRRSAA.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Non-procurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

II. Award Information

Type of Award: Formula grants.

Estimated Available Funds: $767.3 million.

Grant Period: Institutions must expend funds received under this program within 12 months of the obligation of the funds by the Department.

III. Eligibility Information

1. *Eligible Applicants:* Public and private nonprofit IHEs, as defined in sections 101 and 102(c) of the HEA, that are eligible for certain programs under part A of title III and parts A and B of title V of the HEA.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Subgrantees:* Subgrantees are not allowed under this program.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to submit their applications using *Grants.gov.* To register for *Grants.gov,* please visit their ''How to Apply for Grants'' web page (*https://www.grants.gov/applicants/apply-for-grants.html*) or call their Applicant Support helpdesk at 1–800–518–4726.

Each completed application must consist of—

- A complete SF–424;
- Supplemental Information for the SF–424; and
- The Certification and Agreement (C&A) for an Award under Section 2003 for ARP (a)(2).

Note: The applicant must submit the corresponding C&A for the funds requested. Each C&A must be completed and include the correct OPEID and DUNS number of the institution requesting funds. Each grantee will receive the amount calculated for them

and listed in the ARP (a)(2) MSI Allocation Table.

2. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review to make timely awards.

3. *Funding Restrictions:* We specify funding restrictions in the Certificate and Agreement.

4. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* In general, to do business with the Department, you must—

(a) Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

(b) Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

(c) Provide your DUNS number and TIN on your SAM application; and

(d) Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number at the following website: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active. The SAM registration process can take approximately seven business days but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. If you want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN.

If you are currently registered with SAM, you may not need to make any changes. However, please make sure that the TIN associated with your DUNS number is correct. Also, note that you will need to update your registration annually. This process may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, please see our *SAM.gov* Tip Sheet, at: *https://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, in order to submit your application via *Grants.gov,* you must (1) register as an applicant using your DUNS number and (2) be designated by your organization's E-Biz Point of Contact as an Authorized Organization Representative (AOR). Details on these steps are outlined at the following *Grants.gov* web page: *https://www.grants.gov/web/grants/register.html.*

V. Award Administration Information

1. *Award Notices:* If you receive a grant award under this program, we will send you a Grant Award Notification (GAN) or an email containing a link to access an electronic version of your GAN.

2. *Reporting:* Reporting requirements are specified in the C&A.

VI. Other Information

Accessible Format: Individuals with disabilities can obtain this document in an accessible format on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or other accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov/.* At this site, you can view this document, and other documents of this Department published in the **Federal Register**, in text or 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.

Annmarie Weisman,

Deputy Assistant Secretary for Policy, Planning and Innovation, Office of Postsecondary Education.

American Rescue Plan Act of 2021

Supplemental Agreement for an Award Under ARP (a)(2) (ALN 84.425 J, K, L, M)

Supplemental Grant Funds

The terms, conditions, and requirements governing your institution's (Recipient's) use of these supplemental grant funds awarded pursuant to section 2003 of the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) (supplemental award or grant) by the U.S. Department of Education (Department) are governed by section 2003 of the ARP and section 314 of the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (CRRSAA) (Pub. L. 116–260) and the following terms and conditions of this Supplemental Agreement.

BY DRAWING DOWN THESE GRANT FUNDS, YOU AGREE TO BE BOUND BY THE CONDITIONS SET FORTH ON BEHALF OF THE INSTITUTION YOU REPRESENT, AND YOU WARRANT THAT YOU HAVE THE AUTHORITY TO BIND THE INSTITUTION TO THE FOLLOWING CONDITIONS

Use of Supplemental Grant Funds

1. Section 314(a)(2) of CRRSAA authorizes the Secretary to make additional awards under parts A and B of title III, parts A and B of title V, and subpart 4 of part A of title VII of the Higher Education Act of 1965, as amended (''HEA''), to address needs directly related to the coronavirus. These awards are in addition to awards made in Section 2003 for the ARP funding stream and have been allocated by the Secretary proportionally to such programs based on the relative share of funding appropriated to such programs in the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94).

2. Pursuant to Section 314(c) of CRRSAA, Recipient may use this award to defray expenses associated with the coronavirus (including lost revenue, reimbursement for expenses already incurred, technology costs associated with a transition to distance education, faculty and staff trainings, and payroll); and make additional emergency financial grants to students, which may be used for any component of the student's cost of attendance or for emergency costs that arise due to

coronavirus, such as tuition, food, housing, health care (including mental health care), or child care.

3. Under section 2003(5) of the ARP, Recipient must use a portion of their funds received under this supplemental award to (a) implement evidence-based practices to monitor and suppress coronavirus in accordance with public health guidelines and (b) conduct direct outreach to financial aid applicants about the opportunity to receive a financial aid adjustment due to the recent unemployment of a family member or independent student, or other circumstances, described in section 479A of the HEA (20 U.S.C. 1087tt).

4. The Secretary urges Recipient to devote the maximum amount of funds possible to emergency financial aid grants to students. The Secretary urges Recipient to take strong measures to ensure that emergency financial aid grants to students are made to the maximum extent possible.

5. Recipient acknowledges that no supplemental grant funds may be used to fund construction; acquisition of real property; contractors for the provision of pre-enrollment recruitment activities; marketing or recruitment; endowments; capital outlays associated with facilities related to athletics, sectarian instruction, or religious worship; senior administrator or executive salaries, benefits, bonuses, contracts, incentives; stock buybacks, shareholder dividends, capital distributions, and stock options; or any other cash or other benefit for a senior administrator or executive.

6. Recipient acknowledges that it may voluntarily decline all or a portion of its ARP (a)(2) funds. The recipient may indicate this by submitting the Voluntary Decline of HEERF form (OMB Control Number 1840–0856) to the Department by August 11, 2021. Recipient further acknowledges if it submits this form, it will be ineligible for the future redistribution of ARP HEERF grant funds to other institutions with greater needs due to the coronavirus.

Grant Administration

7. Recipient acknowledges that consistent with 2 CFR 200.305, it must minimize the time between drawing down funds from G5 and paying incurred obligations (liquidation). Recipient further acknowledges that if it draws down funds and does not pay the incurred obligations (liquidates) within three calendar days it may be subject to heightened scrutiny by the Department, Recipient's auditors, and/or the Department's Office of Inspector General (OIG). Recipient further acknowledges that returning funds pursuant to mistakes in drawing down excessive grant funds in advance of need may also be subject to heightened scrutiny by the Department, Recipient's auditors, and/or the Department's OIG. Finally, Recipient acknowledges that it must maintain drawn down grant funds in an interest-bearing account, and any interest earned on all Federal grant funds above $500 (all Federal grants together) during an institution's fiscal year must be returned (remitted) to the Federal government via a process described here: *https://www2.ed.gov/documents/funding-101/g5-returning-interest.pdf.*

8. Recipient may charge indirect costs to supplemental funds made available under this award consistent with its negotiated indirect cost rate agreement. If Recipient does not have a current negotiated indirect cost rate with its cognizant agency for indirect costs, it may appropriately charge the *de minimis* rate of ten percent of Modified Total Direct Costs (MTDC) under 2 CFR 200.414. Recipient may also charge reasonable direct administrative costs to the supplemental funds made available under this award.

9. Recipient acknowledges that any obligation under this grant (pre-award costs pursuant to 2 CFR 200.458) must have been incurred on or after March 13, 2020, the date of the declaration of a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (85 FR 15337).

10. Recipient must promptly and to the greatest extent practicable expend all grant funds from this award within the one-year period of performance (2 CFR 200.77) specified in Box 6 of this Grant Award Notification (GAN).

11. Recipient must, to the greatest extent practicable, continue to pay its employees and contractors during the period of any disruptions or closures related to coronavirus pursuant to section 315 of the CRRSAA.

12. Recipient acknowledges that its failure to draw down any amount ($1 or more) of its HEERF grant funds from the institution's HEERF account within 90 days of the date of this supplemental award will constitute nonacceptance of the terms, conditions, and requirements of this Supplemental Agreement and of these supplemental grant funds. In such event, the Department, in its sole discretion, may choose to deobligate these supplemental grant funds or take other appropriate administrative action, up to and including terminating the grant award pursuant to 2 CFR 200.340.

Reporting and Accountability

13. Recipient must promptly and timely provide a detailed accounting of the use and expenditure of the funds provided by this supplemental award in such manner and with such frequency as the Secretary may require. Recipient acknowledges the Department may require additional or more frequent reporting to be specified by the Secretary.

14. Recipient must comply with all requirements of the Single Audit Act Amendments of 1996, 31 U.S.C. 7501, *et seq.* (Single Audit Act) and all applicable auditing standards. Considering that the HEERF grant program is a new program not previously audited or subjected to Department oversight, and the inherent risk that comes with a new program, the Department strongly suggests that the HEERF grant program be audited as a major program in the first fiscal year(s) that the institution received a HEERF grant.

15. Recipient acknowledges it is under a continuing affirmative duty to inform the Department if Recipient is to lose its accreditation, close or terminate operations as an institution, or merge with another institution. In such cases, Recipient must promptly notify in writing the assigned education program officer contact in Box 3. Additionally, Recipient must promptly notify the assigned education program officer if the Recipient's Authorized Representative changes.

16. Recipient must cooperate with any examination of records with respect to the advanced funds by making records and authorized individuals available when requested, whether by (a) the Department and/or its OIG; or (b) any other Federal agency, commission, or department in the lawful exercise of its jurisdiction and authority. Recipient must retain all financial records, supporting documents, statistical records, and all other non-Federal entity records pertinent to a Federal award for a period of three years from the date of submission of the final expenditure report pursuant to 2 CFR 200.334.

17. Recipient acknowledges that failure to comply with this Supplemental Agreement, its terms and conditions, and/or all relevant provisions and requirements of the CRRSAA or ARP or any other applicable law may result in Recipient's liability under the False Claims Act, 31 U.S.C. 3729, *et seq.;* OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of

the Department in 2 CFR part 3485; 18 U.S.C. 1001, as appropriate; and all of the laws and regulations referenced in the ''Applicable Law'' section of this Supplemental Agreement, below.

Applicable Law

18. Recipient must comply with all applicable assurances in OMB Standard Forms (SF) SF–424B and SF–424D (Assurances for Non-Construction and Assurances for Construction Programs), including the assurances relating to the legal authority to apply for assistance; access to records; conflict of interest; nondiscrimination; Hatch Act provisions; labor standards; Single Audit Act; and the general agreement to comply with all applicable Federal laws, executive orders, and regulations.

19. Recipient certifies that with respect to the certification regarding lobbying in Department Form 80–0013, no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making or supplementing of Federal grants under this program; Recipient must complete and submit Standard Form-LLL, ''Disclosure Form to Report Lobbying,'' when required (34 CFR part 82, Appendix B).

20. Recipient must comply with the provisions of all applicable acts, regulations and assurances; the following provisions of *Education Department General Administrative Regulations* (EDGAR) 34 CFR parts 75, 77, 81, 82, 84, 86, 97, 98, and 99; the *OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)* in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485; and the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

[FR Doc. 2021–16348 Filed 7–30–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2021–SCC–0066]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Common Core of Data (CCD) School-Level Finance Survey (SLFS) 2021–2023

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing a revision of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before September 1, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carrie Clarady, (202) 245–6347.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Common Core of Data (CCD) School-Level Finance Survey (SLFS) 2021–2023.

OMB Control Number: 1850–0930.

Type of Review: Revision of a currently approved collection.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 306.

Total Estimated Number of Annual Burden Hours: 4,938.

Abstract: NCES annually publishes comprehensive data on the finances of public elementary/secondary schools through the Common Core of Data (CCD). For numerous years, these data have been released at the state level through the National Public Education Financial Survey (NPEFS) (OMB#1850–0067) and at the school district level through the Local Education Agency (School District) Finance Survey (F–33). (OMB# 0607–0700). There is a significant demand for finance data at the school level. Policymakers, researchers, and the public have long voiced concerns about the equitable distribution of school funding within and across school districts. School-level finance data addresses the need for reliable and unbiased measures that can be utilized to compare how resources are distributed among schools within local districts. Education expenditure data are now available at the school level through the School-Level Finance Survey (SLFS). The School-Level Finance Survey (SLFS) data collection is conducted annually by the National Center for Education Statistics (NCES), within the U.S. Department of Education (ED). In November of 2018, the Office of Management and Budget (OMB) approved changes to the SLFS wherein variables have been added to make the SLFS directly analogous to the F–33 Survey and to the Every Student Succeeds Act (ESSA) provisions on reporting expenditures per-pupil at the local education agency (LEA) and school-level. This request is to collect SLFS data for FY 2021, 2022, and 2023.

Dated: July 27, 2021.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–16359 Filed 7–30–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2021–SCC–0065]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Federal Student Loan Program: Internship/Residency and Loan Debt Burden Forbearance Forms

AGENCY: Federal Student Aid (FSA), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is proposing an extension without change of a currently approved collection.

DATES: Interested persons are invited to submit comments on or before September 1, 2021.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this information collection request by selecting ''Department of Education'' under ''Currently Under Review,'' then check ''Only Show ICR for Public Comment'' checkbox. Comments may also be sent to *ICDocketmgr@ed.gov.*

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Beth Grebeldinger, 202–377–4018.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Federal Student Loan Program: Internship/Residency and Loan Debt Burden Forbearance Forms.

OMB Control Number: 1845–0018.

Type of Review: An extension without change of a currently approved collection.

Respondents/Affected Public: Individuals and Households.

Total Estimated Number of Annual Responses: 27,042.

Total Estimated Number of Annual Burden Hours: 6,393.

Abstract: These forms serve as the means by which borrowers in the William D. Ford Federal Direct Loan (Direct Loan), Federal Family Education Loan (FFEL) and the Federal Perkins Loan (Perkins Loan) Programs may request forbearance of repayment on their loans if they meet certain conditions. The U.S. Department of Education and other loan holders uses the information collected on these forms to determine whether a borrower meets the eligibility requirements for the specific type of forbearance.

Dated: July 28, 2021.

Kate Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2021–16412 Filed 7–30–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

Notice Inviting Applications for Funds Under the Higher Education Emergency Relief Fund (HEERF), Section 2003 of the American Rescue Plan (ARP) for Institutions of Higher Education (IHE) That Meet the Criteria as a Strengthening Institutions Program (SIP)

AGENCY: Office of Postsecondary Education, Department of Education.

ACTION: Notice.

SUMMARY: The Secretary is announcing the availability of new HEERF funding for the ARP (a)(2) grant program authorized under ARP section 2003(2) and inviting applications under Assistance Listing Number (ALN) 84.425M from eligible public and private nonprofit IHEs to address needs directly related to the coronavirus. These awards are in addition to the ARP (a)(1) grant funds and have been allocated by the Secretary proportionally based on the relative share of funding appropriated to SIP in the Further Consolidated Appropriations Act, 2020. The IHEs eligible for this funding include institutions eligible for SIP that did not receive funding under section 314(a)(2) of the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (CRRSAA) and that are included in the ARP (a)(2) allocation table.

This notice relates to the approved information collections under OMB control numbers 1801–0005 and 1840–0842.

DATES:

Applications Available: August 2, 2021.

Deadline for Transmittal of Applications: Applications will be accepted on a rolling basis until October 1, 2021.

ADDRESSES: For the addresses to obtain and submit an application, please refer to the Common Instructions for Applicants to the Department of Education Discretionary Grant Programs, published in the **Federal Register** on February 13, 2019 (84 FR 3768) and available at *https://www.federalregister.gov/documents/2019/02/13/2019-02206/common-instructions-for-applicants-to-department-of-education-discretionary-grant-programs.*

FOR FURTHER INFORMATION CONTACT: Karen Epps, U.S. Department of Education, 400 Maryland Avenue SW, room 250–64, Washington, DC 20202. Department of Education HEERF Customer Care Center, *Phone:* (202) 377–3711. *Email: HEERF@ed.gov.* Please also visit the HEERF website at: *https://www2.ed.gov/about/offices/list/ope/arp.html.*

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll-free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Full Text of Announcement

Background: On March 11, 2021, the President signed the ARP into law (Pub. L. 117–2). This law makes available approximately $39.6 billion for IHEs under HEERF, with funding appropriated through existing programs previously authorized under the CRRSAA.

With this notice, the Secretary is announcing the availability of HEERF grant funds under the ARP (a)(2) SIP program (ALN 84.425M).

Eligible institutions are institutions of higher education, as defined in sections 101 and 102(c) of the Higher Education Act of 1965, as amended (HEA), 20 U.S.C. 1001 and 1002(c). Allocations for these eligible IHEs will be calculated according to the formulas in ARP section 2003(2) and CRRSAA section 314(a)(2). Under ARP section 2003, grant awards under this program may be used to (1) defray expenses associated with the coronavirus, including lost revenue, reimbursement for expenses already incurred, technology costs associated with transitioning to distance education, faculty and staff training, and payroll; and (2) provide financial aid grants to students (including students exclusively enrolled in distance education), which may be used for any component of the student's cost of attendance or emergency costs due to the coronavirus, such as tuition, food, housing, health care, mental health care, or child care. In making financial aid grants to students, an institution must prioritize grants to students with exceptional need, such as Pell recipient students. IHEs are urged to make financial aid grants to students to the maximum extent possible.

Additionally, under ARP section 2003(5), IHEs must use a portion of their funds under ALN 84.425M to (1) implement evidence-based practices to monitor and suppress coronavirus in accordance with the public health guidelines; and (2) conduct direct outreach to financial aid applicants about the opportunity to receive a financial aid adjustment due to recent unemployment status or other changes in financial circumstances as described in section 479A of the HEA (20 U.S.C. 1087tt).

The Department will award supplemental funds to eligible IHEs that received a section 314(a)(2) award under the CRRSAA, ALN 84.425M (identified by a Grant Award beginning with P425Mxx). No action is required by eligible institutions to receive these supplemental awards. The project director identified on the most current Grant Award Notification (GAN) will automatically receive an email indicating a supplemental award has been made to your institution. Please note that drawing down any amount of these supplemental funds constitutes an institution's acceptance of the new ARP terms and conditions and a new Supplemental Agreement, which are attached to this notice for reference.

IHEs that have not yet complied with the reporting requirements of the HEERF may receive delayed supplemental ARP (a)(2) awards and/or may receive awards with a restriction on the ability to drawdown those awarded funds (route payment status) until the institution has satisfied its HEERF reporting obligations.

IHEs that did not receive a CRRSAA section 314(a)(2) award but are on the Department's section 2003(2) ARP SIP Allocation Table may apply for and receive an ARP (a)(2) SIP grant award. The Department must receive applications from such institutions within 60 days of the publication of this notice.

Program Authority: Section 2003 of the ARP and section 314 of the CRRSAA.

Applicable Regulations: (a) The Education Department General Administrative Regulations in 34 CFR parts 75, 77, 81, 82, 84, 86, 97, 98, and 99. (b) The Office of Management and Budget Guidelines to Agencies on Governmentwide Debarment and Suspension (Non-procurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485. (c) The Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

II. Award Information

Type of Award: Formula grants.

Estimated Available Funds: $421.6 million.

Grant Period: Institutions must expend funds received under this program within 12 months of obligation of the funds by the Department.

III. Eligibility Information

1. *Eligible Applicants:* Public and private nonprofit IHEs, as defined in section 101 and section 102(c) of the HEA, and that appear on the ARP (a)(2) SIP Allocation Table.

2. *Cost Sharing or Matching:* This program does not require cost sharing or matching.

3. *Subgrantees:* Subgrantees are not allowed under this program.

IV. Application and Submission Information

1. *Application Submission Instructions:* Applicants are required to submit their applications using *Grants.gov*. To register for *Grants.gov*, please visit their ''How to Apply for Grants'' web page (*https://www.grants.gov/applicants/apply-for-grants.html*) or call their Applicant Support helpdesk at 1–800–518–4726. Each completed application must consist of—

- A complete SF–424;
- Supplemental Information for the SF–424; and
- A Certification and Agreement (C&A) for an Award under Section 2003 for ARP (a)(2).

Note: The applicant must submit the corresponding C&A for the funds requested. The C&A must be completed and include the correct OPE ID and DUNS number of the institution requesting funds. Each grantee will receive the amount calculated for them and listed in the ARP (a)(2) SIP Allocation Table.

2. *Intergovernmental Review:* This program is subject to Executive Order 12372 and the regulations in 34 CFR part 79. However, under 34 CFR 79.8(a), we waive intergovernmental review to make timely awards.

3. *Funding Restrictions:* We specify funding restrictions in the C&A or Supplemental Agreement.

4. *Data Universal Numbering System Number, Taxpayer Identification Number, and System for Award Management:* In general, to do business with the Department, you must—

(a) Have a Data Universal Numbering System (DUNS) number and a Taxpayer Identification Number (TIN);

(b) Register both your DUNS number and TIN with the System for Award Management (SAM), the Government's primary registrant database;

(c) Provide your DUNS number and TIN on your SAM application; and

(d) Maintain an active SAM registration with current information while your application is under review by the Department and, if you are awarded a grant, during the project period.

You can obtain a DUNS number from Dun and Bradstreet at the following website: *http://fedgov.dnb.com/webform.* A DUNS number can be created within one to two business days.

If you are a corporate entity, agency, institution, or organization, you can obtain a TIN from the Internal Revenue Service. If you are an individual, you can obtain a TIN from the Internal Revenue Service or the Social Security Administration. If you need a new TIN, please allow two to five weeks for your TIN to become active.

The SAM registration process can take approximately seven business days, but may take upwards of several weeks, depending on the completeness and accuracy of the data you enter into the SAM database. If you think you might want to apply for Federal financial assistance under a program administered by the Department, please allow sufficient time to obtain and register your DUNS number and TIN.

If you are currently registered with SAM, you may not need to make any changes. However, please make certain that the TIN associated with your DUNS

number is correct. Also note that you will need to update your registration annually. This may take three or more business days.

Information about SAM is available at *www.SAM.gov.* To further assist you with obtaining and registering your DUNS number and TIN in SAM or updating your existing SAM account, please see our *SAM.gov* Tip Sheet at: *https://www2.ed.gov/fund/grant/apply/sam-faqs.html.*

In addition, in order to submit your application via *Grants.gov,* you must (1) register as an applicant using your DUNS number and (2) be designated by your organization's E-Biz Point of Contact as an Authorized Organization Representative (AOR). Details on these steps are outlined at the following *Grants.gov* web page: *https://www.grants.gov/web/grants/register.html.*

V. Award Administration Information

1. *Award Notices:* If you receive a grant award under this program, we will send you a Grant Award Notification (GAN), or an email containing a link to access an electronic version of your GAN.

2. *Reporting:* Reporting requirements are specified in the C&A or Supplemental Agreement.

VI. Other Information

Accessible Format: Individuals with disabilities can obtain this document in an accessible format on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**. The Department will provide the requestor with an accessible format that may include Rich Text Format (RTF) or text format (txt), a thumb drive, an MP3 file, braille, large print, audiotape, or compact disc, or another accessible format.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. You may access the official edition of the **Federal Register** and the Code of Federal Regulations at *www.govinfo.gov.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or 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.

Annmarie Weisman,

Deputy Assistant Secretary for Policy, Planning and Innovation, Office of Postsecondary Education.

American Rescue Plan Act of 2021

Supplemental Agreement for an Award Under ARP (a)(2) (ALN 84.425 J, K, L, M)

Supplemental Grant Funds

The terms, conditions, and requirements governing your institution's (Recipient's) use of these supplemental grant funds awarded pursuant to section 2003 of the American Rescue Plan Act of 2021 (ARP) (Pub. L. 117–2) (supplemental award or grant) by the U.S. Department of Education (Department) are governed by section 2003 of the ARP and section 314 of the Coronavirus Response and Relief Supplemental Appropriations Act, 2021 (CRRSAA) (Pub. L. 116–260) and the following terms and conditions of this Supplemental Agreement.

BY DRAWING DOWN THESE GRANT FUNDS, YOU AGREE TO BE BOUND BY THE CONDITIONS SET FORTH ON BEHALF OF THE INSTITUTION YOU REPRESENT, AND YOU WARRANT THAT YOU HAVE THE AUTHORITY TO BIND THE INSTITUTION TO THE FOLLOWING CONDITIONS

Use of Supplemental Grant Funds

1. Section 314(a)(2) of CRRSAA authorizes the Secretary to make additional awards under parts A and B of title III, parts A and B of title V, and subpart 4 of part A of title VII of the Higher Education Act of 1965, as amended (''HEA''), to address needs directly related to the coronavirus. These awards are in addition to awards made in Section 2003 for the ARP funding stream and have been allocated by the Secretary proportionally to such programs based on the relative share of funding appropriated to such programs in the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94).

2. Pursuant to Section 314(c) of CRRSAA, Recipient may use this award to defray expenses associated with the coronavirus (including lost revenue, reimbursement for expenses already incurred, technology costs associated with a transition to distance education, faculty and staff trainings, and payroll); and make additional emergency financial grants to students, which may be used for any component of the student's cost of attendance or for emergency costs that arise due to coronavirus, such as tuition, food, housing, health care (including mental health care), or child care.

3. Under section 2003(5) of the ARP, Recipient must use a portion of their funds received under this supplemental award to (a) implement evidence-based practices to monitor and suppress the coronavirus in accordance with public health guidelines and (b) conduct direct outreach to financial aid applicants about the opportunity to receive a financial aid adjustment due to the recent unemployment of a family member or independent student, or other circumstances, described in section 479A of the HEA (20 U.S.C. 1087tt).

4. The Secretary urges Recipient to devote the maximum amount of funds possible to emergency financial aid grants to students. The Secretary urges Recipient to take strong measures to ensure that emergency financial aid grants to students are made to the maximum extent possible.

5. Recipient acknowledges that no supplemental grant funds may be used to fund construction; acquisition of real property; contractors for the provision of pre-enrollment recruitment activities; marketing or recruitment; endowments; capital outlays associated with facilities related to athletics, sectarian instruction, or religious worship; senior administrator or executive salaries, benefits, bonuses, contracts, incentives; stock buybacks, shareholder dividends, capital distributions, and stock options; or any other cash or other benefit for a senior administrator or executive.

6. Recipient acknowledges that it may voluntarily decline all or a portion of its ARP (a)(2) funds. The recipient may indicate this by submitting the Voluntary Decline of HEERF form (OMB Control Number 1840–0856) to the Department by August 11, 2021. Recipient further acknowledges if it submits this form, it will be ineligible for the future redistribution of ARP HEERF grant funds to other institutions with greater needs due to the coronavirus.

Grant Administration

7. Recipient acknowledges that consistent with 2 CFR 200.305, it must minimize the time between drawing down funds from G5 and paying incurred obligations (liquidation). Recipient further acknowledges that if it draws down funds and does not pay the incurred obligations (liquidates) within three calendar days it may be subject to heightened scrutiny by the Department, Recipient's auditors, and/or the Department's Office of the Inspector General (OIG). Recipient further

acknowledges that returning funds pursuant to mistakes in drawing down excessive grant funds in advance of need may also be subject to heightened scrutiny by the Department, Recipient's auditors, and/or the Department's OIG. Finally, Recipient acknowledges that it must maintain drawn down grant funds in an interest-bearing account, and any interest earned on all Federal grant funds above $500 (all Federal grants together) during an institution's fiscal year must be returned (remitted) to the Federal government via a process described here: *https://www2.ed.gov/documents/funding-101/g5-returning-interest.pdf.*

8. Recipient may charge indirect costs to supplemental funds made available under this award consistent with its negotiated indirect cost rate agreement. If Recipient does not have a current negotiated indirect cost rate with its cognizant agency for indirect costs, it may appropriately charge the *de minimis* rate of ten percent of Modified Total Direct Costs (MTDC) under 2 CFR 200.414. Recipient may also charge reasonable direct administrative costs to the supplemental funds made available under this award.

9. Recipient acknowledges that any obligation under this grant (pre-award costs pursuant to 2 CFR 200.458) must have been incurred on or after March 13, 2020, the date of the declaration of a National Emergency Concerning the Novel Coronavirus Disease (COVID–19) Outbreak (85 FR 15337).

10. Recipient must promptly and to the greatest extent practicable expend all grant funds from this award within the one-year period of performance (2 CFR 200.77) specified in Box 6 of this Grant Award Notification (GAN).

11. Recipient must, to the greatest extent practicable, continue to pay its employees and contractors during the period of any disruptions or closures related to coronavirus pursuant to section 315 of the CRRSAA.

12. Recipient acknowledges that its failure to draw down any amount ($1 or more) of its HEERF grant funds from the institution's HEERF account within 90 days of the date of this supplemental award will constitute nonacceptance of the terms, conditions, and requirements of this Supplemental Agreement and of these supplemental grant funds. In such event, the Department, in its sole discretion, may choose to deobligate these supplemental grant funds or take other appropriate administrative action, up to and including terminating the grant award pursuant to 2 CFR 200.340.

Reporting and Accountability

13. Recipient must promptly and timely provide a detailed accounting of the use and expenditure of the funds provided by this supplemental award in such manner and with such frequency as the Secretary may require. Recipient acknowledges the Department may require additional or more frequent reporting to be specified by the Secretary.

14. Recipient must comply with all requirements of the Single Audit Act Amendments of 1996, 31 U.S.C. 7501, *et seq.* (Single Audit Act) and all applicable auditing standards. Considering that the HEERF grant program is a new program not previously audited or subjected to Department oversight, and the inherent risk that comes with a new program, the Department strongly suggests that the HEERF grant program be audited as a major program in the first fiscal year(s) that the institution received a HEERF grant.

15. Recipient acknowledges it is under a continuing affirmative duty to inform the Department if Recipient is to lose its accreditation, close or terminate operations as an institution, or merge with another institution. In such cases, Recipient must promptly notify in writing the assigned education program officer contact in Box 3. Additionally, Recipient must promptly notify the assigned education program officer if the Recipient's Authorized Representative changes.

16. Recipient must cooperate with any examination of records with respect to the advanced funds by making records and authorized individuals available when requested, whether by (a) the Department and/or its OIG; or (b) any other Federal agency, commission, or department in the lawful exercise of its jurisdiction and authority. Recipient must retain all financial records, supporting documents, statistical records, and all other non-Federal entity records pertinent to a Federal award for a period of three years from the date of submission of the final expenditure report pursuant to 2 CFR 200.334.

17. Recipient acknowledges that failure to comply with this Supplemental Agreement, its terms and conditions, and/or all relevant provisions and requirements of the CRRSAA or ARP or any other applicable law may result in Recipient's liability under the False Claims Act, 31 U.S.C. 3729, *et seq.;* OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement) in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485; 18 U.S.C. 1001, as appropriate; and all of the laws and regulations referenced in the ''Applicable Law'' section of this Supplemental Agreement, below.

Applicable Law

18. Recipient must comply with all applicable assurances in OMB Standard Forms (SF) SF–424B and SF–424D (Assurances for Non-Construction and Assurances for Construction Programs), including the assurances relating to the legal authority to apply for assistance; access to records; conflict of interest; nondiscrimination; Hatch Act provisions; labor standards; Single Audit Act; and the general agreement to comply with all applicable Federal laws, executive orders, and regulations.

19. Recipient certifies that with respect to the certification regarding lobbying in Department Form 80–0013, no Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the making or supplementing of Federal grants under this program; Recipient must complete and submit Standard Form–LLL, ''Disclosure Form to Report Lobbying,'' when required (34 CFR part 82, Appendix B).

20. Recipient must comply with the provisions of all applicable acts, regulations and assurances; the following provisions of *Education Department General Administrative Regulations* (EDGAR) 34 CFR parts 75, 77, 81, 82, 84, 86, 97, 98, and 99; the *OMB Guidelines to Agencies on Governmentwide Debarment and Suspension (Nonprocurement)* in 2 CFR part 180, as adopted and amended as regulations of the Department in 2 CFR part 3485; and the *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards* in 2 CFR part 200, as adopted and amended as regulations of the Department in 2 CFR part 3474.

[FR Doc. 2021–16347 Filed 7–30–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2021–SCC–0114]

Agency Information Collection Activities; Comment Request; Progress in International Reading Literacy Study (PIRLS 2021) Main Study Data Collection

AGENCY: Institute for Education Sciences (IES), National Center for Education Statistics (NCES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is requesting the Office of Management and Budget (OMB) to conduct an emergency review of an information collection.

DATES: Approval by the OMB has been requested by July 30, 2021. Interested persons are invited to submit comments on or before September 1, 2021.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2021–SCC–0114. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W208B, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Carrie Clarady, 202–245–6347.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Progress in International Reading Literacy Study (PIRLS 2021) Main Study Data Collection.

OMB Control Number: 1850–0645.

Type of Review: A revision of an approved information collection.

Respondents/Affected Public: Individuals or Households.

Total Estimated Number of Annual Responses: 31,028.

Total Estimated Number of Annual Burden Hours: 10,716.

Abstract: The Progress in International Reading Literacy Study (PIRLS) is coordinated by the International Association for the Evaluation of Educational Achievement (IEA), an international collective of research organizations and government agencies that create the assessment framework, the assessment instrument, and background questionnaires. The IEA decides and agrees upon a common set of standards and procedures for collecting and reporting PIRLS data, and defines the studies' timeline, all of which must be followed by all participating countries. As a result, PIRLS is able to provide a reliable and comparable measure of student skills in participating countries. In the U.S., the National Center for Education Statistics (NCES) conducts this study, with support from U.S. Department of Education contractors, and works with the IEA to ensure proper implementation of the study and adoption of practices in adherence to the IEA's standards. Participation in PIRLS allows NCES to meet its mandate of acquiring and disseminating data on educational activities and student achievement in the U.S. compared with foreign nations [The Educational Sciences Reform Act of 2002 (ESRA 2002) 20 U.S.C. 9543]. PIRLS is an international assessment of fourth-grade students' achievement in reading. PIRLS reports on four benchmarks in reading achievement at grade 4 (Advanced, High, Medium, and Low) and on a variety of issues related to the education context for the students in the sample, including instructional practices, school resources, curriculum implementation, and learning supports outside of school. Since its inception in 2001, PIRLS has continued to assess students every 5 years (2001, 2006, 2011, and 2016), with the next PIRLS assessment, PIRLS 2021, being the fifth iteration of the study. Participation in this study by the United States at regular intervals provides data on student achievement and on current and past education policies and a comparison of U.S. education policies and student performance with those of the U.S. international counterparts. In PIRLS 2016, 58 education systems participated. The U.S. will participate in PIRLS 2021 to continue to monitor the progress of its students compared to that of other nations and to provide data on factors that may influence student achievement. In preparation for the PIRLS 2021 main study, all countries were asked to implement a field test in 2020 in order to evaluate new assessment items and background questions, to ensure practices that promote low exclusion rates, and to ensure that classroom and student sampling procedures proposed for the main study are successful. In selecting a school sample for this purpose, it is important to minimize the burden on schools, districts, and states, while also ensuring that the field test data are collected effectively. PIRLS staff will work to help respondents understand the study's value relative to the burden imposed, and to ensure a high level of school participation. Data collection for the field test in the U.S. occurred from March 1 through April 15, 2020 and involved a sample of 45 public schools and about 1,650 students (selecting two classes from each school). The U.S PIRLS 2021 main study involves a nationally-representative sample of 290 schools and about 9,280 students. Main study data collection was originally scheduled to be completed in Spring 2021, but due to the COVID–19 pandemic the main study has been delayed and will be conducted from September through October 2021. The submission describing the overarching

plan for all phases of the data collection, including the 2021 main study, and requesting approval for all activities, materials, and response burden related to the field test recruitment was approved in April 2019 with a change request in September 2019 (OMB #1850–0645 v.11–12), while the submission describing all aspects of the field test and recruitment for the main study was approved in October 2019 (OMB #1850–0645 v.13). The submission for all aspects of the PIRLS 2021 main study, including data collection activities, with an accompanying 30-day public comment period was approved in May 2020 (OMB #1850–0645 v.14) with a change request in February 2021 (OMB #1850–0645 v.15). In summer 2021, NCES was notified by the IEA that teacher questionnaire data from the United States would not be included in the PIRLS international report or international database. At the same time, IEA requested changes to the school questionnaire to solicit information about the 2020–2021 school year. The exceptional circumstances of the 2021 PIRLS administration in the United States and these other countries (assessing fifth-grade students at the beginning of the academic year rather than fourth-grade students at the end of the academic year) present challenges for reporting and interpreting some PIRLS questionnaire data. This issue impacts other Northern Hemisphere countries administering the PIRLS teacher questionnaire to the teachers of fifth grade students in the fall of 2021. Due to the exclusion of teacher questionnaire data from international reporting and limitations in its use for national analysis, the U.S. PIRLS 2021 administration will no longer include a teacher questionnaire component. In accordance with the IEA's guidance, the school questionnaire has been modified to more adequately characterize the impact of the pandemic on students in countries assessing students at the beginning of fifth grade rather than at the end of the fourth grade. Note, for example, that the school questionnaire now asks questions about resources available to 4th grade students. The aim is to evaluate students at the beginning of their fifth-grade year, in light of what was available to them throughout their fourth-grade year. These changes will facilitate the inclusion of U.S. data in international reports that include findings from the school questionnaire.

Additional Information: An emergency clearance approval for the use of the system is described below due to the following conditions:

• NCES requests emergency clearance to allow us to continue recruiting schools for participation in a Fall 2021 data collection after substantive changes were required to an already approved and finalized data collection plan. The need for immediate clearance is due to the time sensitivity of this data collection, as normal clearance procedures would not allow NCES to follow the mandates set by the sponsoring international organization and make the required changes to the data collection while also respecting the timeline specified for this data collection. NCES will publish a **Federal Register** Notice soliciting 30 days of public comment on this collection concurrent with continued recruitment and data collection.

Dated: July 27, 2021.

Stephanie Valentine,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer.

[FR Doc. 2021–16342 Filed 7–30–21; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Idaho Cleanup Project

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open in-person/virtual hybrid meeting.

SUMMARY: This notice announces an in-person/virtual hybrid meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Idaho Cleanup Project (ICP). The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Wednesday, August 18, 2021; 3:00 p.m.–6:30 p.m.

The opportunity for oral public comment for those attending in-person is at 4:45 p.m. MTN and written public comment received prior to the meeting will be read into the record.

This time is subject to change; please contact the ICP Citizens Advisory Board (CAB) Administrator (below) for confirmation of time prior to the meeting.

ADDRESSES: This hybrid meeting is offered both virtually via Zoom and in-person. To attend virtually, please contact the ICP CAB Administrator (below) no later than 5:00 p.m. MTN on Monday, August 16, 2021.

Board members, Department of Energy (DOE) representatives, agency liaisons, and support staff will participate in-person at: Residence Inn by Marriott Idaho Falls, 635 W Broadway Street, Idaho Falls, ID 83402.

FOR FURTHER INFORMATION CONTACT: Jordan Davies, ICP CAB Administrator, by phone (720) 452–7379 or email *jdavies@northwindgrp.com* or visit the Board's internet homepage at *https://energy.gov/em/icpcab.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to make recommendations to DOE–EM and site management in the areas of environmental restoration, waste management, and related activities.

Tentative Agenda (agenda topics may change up to the day of the meeting; please contact Jordan Davies for the most current agenda):

1. Recent Public Outreach
2. Idaho Cleanup Project Overview
3. Integrated Waste Treatment Unit (IWTU) Update
4. Westbay Well Rehabilitation Update
5. Spent Nuclear Fuel at the Idaho site
6. Indefinite Delivery Indefinite Quantity End State Contracting Model

Public Participation: The in-person/online virtual hybrid meeting is open to the public. Written statements may be filed with the Board no later than 5:00 p.m. MTN on Monday, August 16, 2021 or within seven days after the meeting by sending them to the ICP CAB Administrator at the aforementioned email address. Oral comments may be given by in-person attendees during the aforementioned time. The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make or submit public comments should follow as directed above.

Minutes: Minutes will be available by writing or calling Jordan Davies, ICP CAB Administrator, phone (720) 452–7379 or email *jdavies@northwindgrp.com.* Minutes will also be available at the following website: *https://energy.gov/em/icpcab.*

Signed in Washington, DC, on July 28, 2021.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2021–16445 Filed 7–30–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Agency Information Collection Extension

AGENCY: Office of Small Business Innovation Research and Small Business Technology Transfer (SBIR/STTR), Office of Science, Department of Energy.

ACTION: Submission for Office of Management and Budget (OMB) review; comment request.

SUMMARY: The Department of Energy (DOE) has submitted an information collection request to the OMB for extension under the provisions of the Paperwork Reduction Act of 1995. The information collection requests a three-year extension of its Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Commercialization Survey, OMB Control Number 1910–5166. The proposed collection will satisfy the program requirements of the Small Business Act, including requirements established in the SBIR program reauthorization legislation. DOE will collect the survey data via web-enabled software and provide it to the Small Business Administration (SBA) to maintain information about the DOE SBIR/STTR awards issued through the two programs. This data will be provided by DOE based on information collected from SBIR/STTR awardees. This data will be used by DOE, SBA, and Congress to assess the commercial impact of these two programs.

DATES: Comments regarding this collection must be received on or before September 1, 2021. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, please advise the OMB Desk Officer of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at (202) 395–4718.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Claudia Cantoni, SBIR/STTR Programs Manager, U.S. Department of Energy, 19901 Germantown Road, Germantown, MD 20874–1290. Phone: (240) 255–8590. Email: *claudia.cantoni@science.doe.gov.*

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) *OMB No.:* 1910–5166; (2) *Information Collection Request Title:* Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Commercialization Survey; (3) *Type of Request:* Renewal; (4) *Purpose:* The DOE needs this information to satisfy the program requirements of the Small Business Act, including requirements established in the SBIR program reauthorization legislation, Public Law 106–554 and Public Law 107–50. This data will be collected by the DOE and provided to the Small Business Administration (SBA) to maintain information about SBIR/STTR awards issued through the two programs. This data will be provided by DOE based on information collected from SBIR/STTR awardees. This data will be used by DOE, SBA, and Congress to assess the commercial impact of these two programs; (5) *Annual Estimated Number of Respondents:* 1,000; (6) *Annual Estimated Number of Total Responses:* 1,000; (7) *Annual Estimated Number of Burden Hours:* 1,000; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $83,000.

Statutory Authority: Section 9 of the Small Business Act, as amended, codified at 15 U.S.C. 638(g).

Signing Authority

This document of the Department of Energy was signed on July 27, 2021, by Manny Oliver, Director, Office of Small Business Innovation Research and Small Business Technology Transfer, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on July 27, 2021.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2021–16345 Filed 7–30–21; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. AD20–11–000]

Extension of Non-Statutory Deadlines; Supplemental Notice Waiving Regulations

On May 8, 2020, in response to emergency conditions caused by Novel Coronavirus Disease (COVID–19), the Secretary waived through September 1, 2020, the Commission's regulations that require that filings with the Commission be notarized or supported by sworn declarations.[1] On January 22, 2021, the Secretary extended this waiver through July 30, 2021.[2]

The National Emergency continues.[3] However, companies and individuals are returning to their workplaces or are determining how to permit a safe return to their workplaces in the coming months. Therefore, there is good cause to extend through and including January 1, 2022, waiver of the Commission's regulations that require that filings with the Commission be notarized or supported by sworn declarations as provided in the January 2021 Notice.[4]

Dated: July 26, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–16424 Filed 7–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–9224–000]

Young, Theresa; Notice of Filing

Take notice that on July 20, 2021, Theresa Young submitted for filing, application for authority to hold interlocking positions, pursuant to

[1] *See, e.g.,* 18 CFR 45.7 (2020) (requiring application for authority to hold interlocking positions to be verified under oath).

[2] Supplemental Notice Waiving Regulations, *Extension of Non-Statutory Deadlines,* Docket No. AD20–11–000 (Jan. 22, 2021) (January 2021 Notice).

[3] A Letter on the Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic (Feb. 24, 2021), *https://www.whitehouse.gov/briefing-room/statements-releases/2021/02/24/a-letter-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic/.*

[4] The Commission concurrently is issuing an order in Docket No. EL20–37–000 granting blanket waiver of requirements to hold meetings in person and/or to provide or obtain notarized documents in open access transmission tariffs and other Commission-jurisdictional agreements through and including January 1, 2022.

section 305(b) of the Federal Power Act, 16 U.S.C. 825d (b) and Part 45.8 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR part 45.8.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Comment Date: 5:00 p.m. Eastern Time on August 10, 2021.

Dated: July 26, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–16425 Filed 7–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR21–10–000]

Notice of Request for Emergency Relief; Airlines for America; Reno-Tahoe Airport Authority; Alaska Air Group, Inc.; Allegiant Air; American Airlines, Inc.; Delta Air Lines, Inc.; Federal Express Corp.; Frontier Airlines; JetBlue Airways Corp.; National Air Carrier Association; Southwest Airlines Co.; World Fuel Services, Inc.

Take notice that on July 26, 2021, Airlines for America, Reno-Tahoe Airport Authority, Alaska Air Group, Inc., Allegiant Air, American Airlines, Inc., Delta Air Lines, Inc., Federal Express Corporation, Frontier Airlines, JetBlue Airways Corporation, National Air Carrier Association, Southwest Airlines Co., and World Fuel Services, Inc. (collectively, Movants) filed a request for the Commission to exercise its emergency powers pursuant to Section 1(15) of the Interstate Commerce Act (ICA), to allow, or if necessary direct, SFPP, L.P. (SFPP) to temporarily provide priority treatment to jet fuel shipments from origins on SFPP's North Line to Reno, Nevada. Movants submit that emergency action from the Commission is necessary to prevent jet fuel shortages, cancelled flights, and disruption to critical passenger and cargo transportation at Reno-Tahoe International Airport throughout August. Movants request that the Commission direct SFPP to immediately give priority in transportation to jet fuel and provide an additional 20,000 barrels of jet fuel capacity, or 541 barrels per day, above the jet fuel already scheduled for shipment through Monday, September 6, 2021.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or a motion to intervene, as appropriate. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission strongly encourages electronic filing of comments, protests, and interventions in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the eLibrary link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free (886) 208–3676 or TYY, (202) (502–8659).

Comments due: 5:00 p.m. Eastern time on July 27, 2021.

Dated: July 26, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–16421 Filed 7–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2511–000]

Aquamarine Lessee, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Aquamarine Lessee, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and

385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 16, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 27, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16415 Filed 7–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG21–206–000.
Applicants: Avangrid Renewables, LLC.
Description: Self-Certification of WHole Sale Generator Status of Avangrid Renewables, LLC.
Filed Date: 7/27/21.
Accession Number: 20210727–5091.
Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: EG21–207–000.
Applicants: Dichotomy Power Maine LLC.
Description: Notice of Self-Certification of Exempt Wholesale Generator of Dichotomy Power Maine LLC.
Filed Date: 7/27/21.
Accession Number: 20210727–5138.
Comments Due: 5 p.m. ET 8/17/21.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1910–021.
Applicants: Duquesne Power, LLC, Duquesne Light Company.
Description: Supplement to July 7, 2021 Notice of Change in Status of Duquesne Light Company.
Filed Date: 7/26/21.
Accession Number: 20210726–5238.
Comments Due: 5 p.m. ET 8/16/21.

Docket Numbers: ER17–2341–005.
Applicants: CA Flats Solar 130, LLC.
Description: Notice of Non-Material Change in Status of CA Flats Solar 130, LLC.
Filed Date: 7/22/21.
Accession Number: 20210722–5245.
Comments Due: 5 p.m. ET 8/12/21.

Docket Numbers: ER21–1790–002.
Applicants: California Independent System Operator Corporation.
Description: Compliance filing: 2021–07–26 Load, Exports & Wheeling—Compliance Filing to be effective 7/30/2021.
Filed Date: 7/26/21.
Accession Number: 20210726–5148.
Comments Due: 5 p.m. ET 8/16/21.

Docket Numbers: ER21–2109–000.
Applicants: Wheatridge Solar Energy Center, LLC.
Description: Supplement to June 9, 2021 Wheatridge Solar Energy Center, LLC tariff filing.
Filed Date: 7/23/21.
Accession Number: 20210723–5212.
Comments Due: 5 p.m. ET 8/2/21.

Docket Numbers: ER21–2500–000.
Applicants: Panther Creek Power Operating, LLC.
Description: Request for Limited Waiver of Panther Creek Power Operating, LLC.
Filed Date: 7/22/21.
Accession Number: 20210722–5243.
Comments Due: 5 p.m. ET 8/12/21.

Docket Numbers: ER21–2509–000.
Applicants: ISO New England Inc., Cross-Sound Cable Company, LLC.
Description: Compliance filing: ISO–NE and Cross Sound Cable; Schedule 18 Revisions to be effective 12/31/9998.
Filed Date: 7/26/21.
Accession Number: 20210726–5159.
Comments Due: 5 p.m. ET 8/16/21.

Docket Numbers: ER21–2510–000.
Applicants: Aquamarine Westside, LLC.
Description: Baseline eTariff Filing: Application for MBR Authorization and Requests for Certain Waivers, et al. to be effective 7/27/2021.
Filed Date: 7/26/21.
Accession Number: 20210726–5155.
Comments Due: 5 p.m. ET 8/16/21.

Docket Numbers: ER21–2511–000.
Applicants: Aquamarine Lessee, LLC.
Description: Baseline eTariff Filing: Application for MBR Authorization and Requests for Certain Waivers, et al. to be effective 7/27/2021.
Filed Date: 7/26/21.
Accession Number: 20210726–5157.
Comments Due: 5 p.m. ET 8/16/21.

Docket Numbers: ER21–2512–000.
Applicants: PJM Interconnection, L.L.C.
Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 3324; Queue No. AB1–033 (consent) to be effective 10/13/2017.
Filed Date: 7/27/21.
Accession Number: 20210727–5013.
Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2513–000.
Applicants: Golden Spread Electric Cooperative, Inc.
Description: Compliance filing: Order No. 676–I Compliance and Waiver to be effective 12/31/9998.
Filed Date: 7/27/21.
Accession Number: 20210727–5054.
Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2514–000.
Applicants: Public Service Company of New Mexico.
Description: Compliance filing: PNM's Compliance Filing with Order No. 676–I to be effective 10/27/2021.
Filed Date: 7/27/21.
Accession Number: 20210727–5055.
Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2515–000.

Applicants: Dominion Energy South Carolina, Inc.

Description: Compliance filing: Order 676–I Compliance filing to be effective 12/31/9998.

Filed Date: 7/27/21.

Accession Number: 20210727–5062.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2516–000.

Applicants: Tucson Electric Power Company.

Description: Compliance filing: Order No. 676–I Compliance Filing to be effective 10/27/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5063.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2517–000.

Applicants: UNS Electric, Inc.

Description: Compliance filing: Order No. 676–I Compliance Filing to be effective 10/27/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5064.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2518–000.

Applicants: PJM Interconnection, L.L.C., Virginia Electric and Power Company.

Description: § 205(d) Rate Filing: Dominion submits revisions to OATT, Att. H–16A re: Unfunded Reserves to be effective 1/1/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5068.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2519–000.

Applicants: Deseret Generation & Transmission Co-operative, Inc.

Description: Compliance filing: Order No. 676–I Compliance to be effective 12/31/9998.

Filed Date: 7/27/21.

Accession Number: 20210727–5070.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2520–000.

Applicants: MATL LLP.

Description: Compliance filing: Order 676–I Compliance Filing and Continued Waiver Request to be effective 12/31/9998.

Filed Date: 7/27/21.

Accession Number: 20210727–5078.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2521–000.

Applicants: Broadlands Wind Farm LLC.

Description: Baseline eTariff Filing: Reactive Power Compensation Filing to be effective 9/25/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5080.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2522–000.

Applicants: American Electric Power Service Corporation, PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: AEP submits Update to Attachment 1 of ILDSA, SA No. 1336 7/27 to be effective 7/1/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5092.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2523–000.

Applicants: Gulf Power Company.

Description: Compliance filing: Order No. 676–I Compliance Filing to be effective 12/31/9998.

Filed Date: 7/27/21.

Accession Number: 20210727–5094.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2524–000.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Compliance to Order No. 676–I in Docket No. RM05–5–027 to be effective 10/27/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5104.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2525–000.

Applicants: Alabama Power Company.

Description: Compliance filing: OATT Attachment O Order No. 676–I Compliance Filing to be effective 12/31/9998.

Filed Date: 7/27/21.

Accession Number: 20210727–5114.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2526–000.

Applicants: New York Independent System Operator, Inc.

Description: Compliance filing: NOPR compliance filing of tariff revisions comply with Order No. 676 NAESB WEQ to be effective 10/27/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5124.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2527–000.

Applicants: Puget Sound Energy, Inc.

Description: Compliance filing: Order No. 676–I Notice of Compliance to be effective N/A.

Filed Date: 7/27/21.

Accession Number: 20210727–5127.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2528–000.

Applicants: PacifiCorp.

Description: Tariff Cancellation: Termination of Provo City Operating Agreement to be effective 9/26/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5128.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2529–000.

Applicants: ISO New England Inc., Eversource Energy Service Company (as agent, Green Mountain Power Corporation, New England Power Company, Vermont Transco LLC.

Description: Compliance filing: PTO AC Revisions to Schedules 20A and 21 to Comply with Order No. 676–I to be effective 12/31/9998.

Filed Date: 7/27/21.

Accession Number: 20210727–5134.

Comments Due: 5 p.m. ET 8/17/21.

Docket Numbers: ER21–2530–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: 2021–07–27 Supercluster Tariff Amendment Filing to be effective 9/26/2021.

Filed Date: 7/27/21.

Accession Number: 20210727–5144.

Comments Due: 5 p.m. ET 8/17/21.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH21–15–000.

Applicants: Consumers Energy Company.

Description: CMS Energy Corporation submits FERC–65B Notice of Material Change in Fact to Waiver Notification.

Filed Date: 7/23/21.

Accession Number: 20210723–5215.

Comments Due: 5 p.m. ET 8/13/21.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 27, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16416 Filed 7–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2955–011]

City of Watervliet, New York; Notice of Intent To Prepare an Environmental Assessment

On February 28, 2020, the City of Watervliett, New York filed an application for a subsequent minor license for the 1.25-megawatt Normanskill Hydroelectric Project (Normanskill Project) (FERC No. 2955). The Normanskill Project is located on the Normans Kill in the Town of Guilderland in Albany County, New York. The project is located approximately 22.4 river miles upstream of the mouth of the Hudson River. The project does not occupy federal land.

In accordance with the Commission's regulations, on May 11, 2021, Commission staff issued a notice that the project was ready for environmental analysis (REA notice). Based on the information in the record, including comments filed on the REA notice, staff does not anticipate that licensing the project would constitute a major federal action significantly affecting the quality of the human environment. Therefore, staff intends to prepare an Environmental Assessment (EA) on the application to license the Normanskill Project.

The EA will be issued and circulated for review by all interested parties. All comments filed on the EA will be analyzed by staff and considered in the Commission's final licensing decision.

The application will be processed according to the following schedule. Revisions to the schedule may be made as appropriate.

Milestone	Target date
Commission issues EA	November 2021.[1]
Comments on EA	December 2021.

[1] The Council on Environmental Quality's (CEQ) regulations under 40 CFR 1501.10(b)(1) require that EAs be completed within 1 year of the federal action agency's decision to prepare an EA. This notice establishes the Commission's intent to prepare an EA for the Normanskill Project. Therefore, in accordance with CEQ's regulations, the EA must be issued within 1 year of the issuance date of this notice.

Any questions regarding this notice may be directed to Woohee Choi at (202) 502–6336 or *woohee.choi@ferc.gov.*

Dated: July 27, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–16423 Filed 7–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER21–2510–000]

Aquamarine Westside, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Aquamarine Westside, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 16, 2021.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically may mail similar pleadings to the Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426. Hand delivered submissions in docketed proceedings should be delivered to Health and Human Services, 12225 Wilkins Avenue, Rockville, Maryland 20852.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://www.ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Dated: July 27, 2021.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2021–16414 Filed 7–30–21; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP21–478–000]

Natural Gas Pipeline Company of America LLC; Notice of Request Under Blanket Authorization and Establishing Intervention and Protest Deadline

Take notice that on July 21, 2021, Natural Gas Pipeline Company of America LLC (Natural), 3250 Lacey Road, Suite 700, Downers Grove, Illinois 60515, filed in the above referenced docket a prior notice pursuant to sections 157.205, 157.206, 157.208(b), and 157.216 of the Commission's regulations and its blanket certificate issued in Docket No. CP82–402–000 requesting authorization to: (1) Plug and abandon the inactive injection and withdrawal M–2 Well, including associated surface facilities; (2) abandon by removal the related Cathodic Protection System rectifier; (3) abandon in-place approximately 480 feet of the 6-inch-diameter M10 Lateral; and (4) abandon by removal the 6-inch-diameter M10 Lateral Valve and the interconnect between the M10 Lateral and the 16-inch-diameter M1 Trunkline, all at Natural's Cairo Mount Simon Storage Field in Louisa County, Iowa. Natural asserts that there will be no impact on the Cairo Mount Simon Storage Field's certificated parameters, including total

gas storage inventory, reservoir pressure, reservoir and buffer boundaries, and certificated capacity. Natural estimates the cost of the project to be approximately $234,000, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

In addition to publishing the full text of this document in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print the contents of this document via the internet through the Commission's Home Page (*http://ferc.gov*) using the ''eLibrary'' link. Enter the docket number excluding the last three digits in the docket number field to access the document. At this time, the Commission has suspended access to the Commission's Public Reference Room, due to the proclamation declaring a National Emergency concerning the Novel Coronavirus Disease (COVID–19), issued by the President on March 13, 2020. For assistance, contact the Federal Energy Regulatory Commission at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application should be directed to Kevin L. Palmer, Director, Regulatory Kinder Morgan, Inc., as operator of Natural Gas Pipeline Company of America LLC, 3250 Lacey Road, Suite 700, Downers Grove, Illinois 60515–7918, by telephone at (630) 725–3074 or by email at *kevin_palmer@kindermorgan.com.*

Public Participation

There are three ways to become involved in the Commission's review of this project: you can file a protest to the project, you can file a motion to intervene in the proceeding, and you can file comments on the project. There is no fee or cost for filing protests, motions to intervene, or comments. The deadline for filing protests, motions to intervene, and comments is 5:00 p.m. Eastern Time on September 27, 2021. How to file protests, motions to intervene, and comments is explained below.

Protests

Pursuant to section 157.205 of the Commission's regulations under the NGA,[1] any person [2] or the Commission's staff may file a protest to the request. If no protest is filed within the time allowed or if a protest is filed and then withdrawn within 30 days after the allowed time for filing a protest, the proposed activity shall be deemed to be authorized effective the day after the time allowed for protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request for authorization will be considered by the Commission.

Protests must comply with the requirements specified in section 157.205(e) of the Commission's regulations,[3] and must be submitted by the protest deadline, which is September 27, 2021. A protest may also serve as a motion to intervene so long as the protestor states it also seeks to be an intervenor.

Interventions

Any person has the option to file a motion to intervene in this proceeding. Only intervenors have the right to request rehearing of Commission orders issued in this proceeding and to subsequently challenge the Commission's orders in the U.S. Circuit Courts of Appeal.

To intervene, you must submit a motion to intervene to the Commission in accordance with Rule 214 of the Commission's Rules of Practice and Procedure [4] and the regulations under the NGA [5] by the intervention deadline for the project, which is September 27, 2021. As described further in Rule 214, your motion to intervene must state, to the extent known, your position regarding the proceeding, as well as your interest in the proceeding. For an individual, this could include your status as a landowner, ratepayer, resident of an impacted community, or recreationist. You do not need to have property directly impacted by the project in order to intervene. For more information about motions to intervene, refer to the FERC website at *https://www.ferc.gov/resources/guides/how-to/intervene.asp.*

All timely, unopposed motions to intervene are automatically granted by operation of Rule 214(c)(1). Motions to intervene that are filed after the intervention deadline are untimely and may be denied. Any late-filed motion to intervene must show good cause for being late and must explain why the time limitation should be waived and provide justification by reference to factors set forth in Rule 214(d) of the Commission's Rules and Regulations. A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies (paper or electronic) of all documents filed by the applicant and by all other parties.

Comments

Any person wishing to comment on the project may do so. The Commission considers all comments received about the project in determining the appropriate action to be taken. To ensure that your comments are timely and properly recorded, please submit your comments on or before September 27, 2021. The filing of a comment alone will not serve to make the filer a party to the proceeding. To become a party, you must intervene in the proceeding.

How To File Protests, Interventions, and Comments

There are two ways to submit protests, motions to intervene, and comments. In both instances, please reference the Project docket number CP21–478–000 in your submission. The Commission encourages electronic filing of submissions.

(1) You may file your protest, motion to intervene, and comments by using the Commission's eFiling feature, which is located on the Commission's website (*www.ferc.gov)* under the link to Documents and Filings. New eFiling users must first create an account by clicking on ''eRegister.'' You will be asked to select the type of filing you are making; first select General'' and then select ''Protest'', ''Intervention'', or ''Comment on a Filing.''

The Commission's eFiling staff are available to assist you at (202) 502–8258 or *FercOnlineSupport@ferc.gov.*

(2) You can file a paper copy of your submission. Your submission must reference the Project docket number CP21–478–000.

To mail via USPS, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Washington, DC 20426.

To mail via any other courier, use the following address: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852.

Protests and motions to intervene must be served on the applicant either by mail or email (with a link to the document) at: *kevin_palmer@kindermorgan.com,* 3250 Lacey Road, Suite 700, Downers Grove, Illinois 60515–7918. Any subsequent submissions by an intervenor must be served on the applicant and all other parties to the proceeding. Contact information for parties can be

[1] 18 CFR 157.205.

[2] Persons include individuals, organizations, businesses, municipalities, and other entities. 18 CFR 385.102(d).

[3] 18 CFR 157.205(e).

[4] 18 CFR 385.214.

[5] 18 CFR 157.10.

downloaded from the service list at the eService link on FERC Online.

Tracking the Proceeding

Throughout the proceeding, additional information about the project will be available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC website at *www.ferc.gov* using the ''eLibrary'' link as described above. The eLibrary link also provides access to the texts of all formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. For more information and to register, go to *www.ferc.gov/docs-filing/esubscription.asp.*

Dated: July 27, 2021.

Kimberly D. Bose,

Secretary.

[FR Doc. 2021–16422 Filed 7–30–21; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2017–0750; FRL–8638–01–OCSPP]

Pesticide Registration Review; Interim Decision for Paraquat Dichloride; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This document announces the availability of EPA's interim registration review decision for paraquat dichloride (paraquat).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2021–0015, is available online at *http://www.regulations.gov* or in person at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton 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.*

Due to the public health concerns related to COVID–19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* The Chemical Review Manager for paraquat identified in the Table in Unit IV.

For general information on the registration review program, contact: Melanie Biscoe, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW, Washington, DC 20460–0001; telephone number: (703) 305–7106; email address: *biscoe.melanie@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, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, contact the Chemical Review Manager for paraquat identified in the Table in Unit IV.

B. What is registration review?

Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration, that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed proposed interim decisions for all pesticides listed in the Table in Unit IV. Through this program, EPA is ensuring that each pesticide's registration is based on current scientific and other knowledge, including its effects on human health and the environment.

II. Authority

EPA is conducting its registration review of the chemicals listed in the Table in Unit IV pursuant to section 3(g) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. What Action is the Agency Taking?

Pursuant to 40 CFR 155.58, this notice announces the availability of EPA's interim registration review decision for paraquat. The interim registration review decision is supported by rationales included in the docket established for each chemical.

TABLE 1—REGISTRATION REVIEW INTERIM DECISION BEING ISSUED

Registration Review Case Name and Number	Docket ID Number	Chemical Review Manager and Contact Information
Paraquat Dichloride Case Number 0262	EPA–HQ–OPP–2011–0855	Ana Pinto, *pinto.ana@epa.gov* 703–347–8421.

The proposed interim registration review decision for paraquat was posted to the docket and the public was invited to submit any comments or new information. EPA addressed the comments or information received

during the 80-day comment period for the proposed interim decision in the discussion for paraquat. Comments from the 80-day comment period that were received may or may not have affected the Agency's interim decision. Pursuant to 40 CFR 155.58(c), the registration review case docket for paraquat will remain open until all actions required in the interim decision have been completed.

Background on the registration review program is provided at: *http://www.epa.gov/pesticide-reevaluation.*

Authority: 7 U.S.C. 136 *et seq.*

Dated: July 26, 2021.

Mary Reaves,

Acting Director, Pesticide Re-Evaluation Division, Office of Pesticide Programs.

[FR Doc. 2021–16344 Filed 7–30–21; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[IB Docket No. 16–185; DA 21–898; FRS 40705]

Informal Working Group 3 and Informal Working Group 4 of the World Radiocommunication Conference Advisory Committee Revise Their Meeting Schedules

AGENCY: Federal Communications Commission.

ACTION: Notice.

SUMMARY: This notice advises interested persons that Informal Working Group 3 (IWG–3) and Informal Working Group 4 (IWG–4) of the 2023 World Radiocommunication Conference Advisory Committee (WRC–23 Advisory Committee) have scheduled meetings as set forth below. The meetings are open to the public.

DATES: IWG–4: Wednesday, September 1, 2021 (11:00 a.m.–1:00 p.m. EDT); IWG–3: Wednesday, September 1, 2021 (1:00 p.m.–3:00 p.m. EDT).

ADDRESSES: The meetings will be held virtually.

FOR FURTHER INFORMATION CONTACT: Dante Ibarra, Designated Federal Official, World Radiocommunication Conference Advisory Committee, FCC International Bureau, Global Strategy and Negotiation Division, at *Dante.Ibarra@fcc.gov,* (202) 418–0610 or *WRC-23@fcc.gov.*

SUPPLEMENTARY INFORMATION: The FCC established the Advisory Committee to provide advice, technical support and recommendations relating to the preparation of United States proposals and positions for the 2023 World Radiocommunication Conference (WRC–23).

In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, this notice advises interested persons of the IWG–3 and IWG–4 of the WRC–23 Advisory Committee scheduled meetings. The Commission's WRC–23 website (*www.fcc.gov/wrc-23*) contains the latest information on all scheduled meetings, meeting agendas, and WRC–23 Advisory Committee matters.

The revised schedule of IWG–3 and IWG–4 meetings are as follows:

WRC–23 Advisory Committee

Schedule of Meetings of Informal Working Groups 3 and 4

Informal Working Group 3: Space Services

Contacts

Chair—Zachary Rosenbaum, *zachary.rosenbaum@ses.com,* telephone: (814) 233–7373
Vice Chair—Vacant

FCC Representatives

Clay DeCell, *clay.decell@fcc.gov,* telephone: (202) 418–0803
Kathyrn Medley, *kathyrn.medley@fcc.gov,* telephone: (202) 418–1211
Eric Grodsky, *eric.grodsky@fcc.gov,* telephone: (202) 418–0563
Dante Ibarra, *dante.ibarra@fcc.gov,* telephone: (202) 418–0610

IWG–3—Meeting

Date: Wednesday, September 1, 2021
Time: 1:00 p.m.–3:00 p.m. EDT
WebEx meeting number (access code): 199 562 2904
WebEx meeting password: qPdpJJJR232
Join by phone: +1–415–527–5035 US Toll

Informal Working Group 4: Regulatory Issues

Contacts

Chair – David Goldman, *david.goldman@spacex.com,* telephone: (202) 649–2641
Vice Chair—Giselle Creeser, *giselle.creeser@intelsat.com,* telephone: (703) 559–7851

FCC Representatives

Dante Ibarra, *dante.ibarra@fcc.gov,* telephone: (202) 418–0610
Clay DeCell, *clay.decell@fcc.gov,* telephone: (202) 418–0803

IWG–4—Meeting

Date: Wednesday, September 1, 2021
Time: 11:00 a.m.–1:00 p.m. EDT
WebEx meeting number (access code): 199 742 9498
WebEx meeting password: UdrMTgz7m53
Join by phone: +1–415–527–5035 US Toll

Federal Communications Commission.

Troy Tanner,

Deputy Chief, International Bureau.

[FR Doc. 2021–16353 Filed 7–30–21; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–21–21EE]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments (CDC–RFA–PS21–2103) to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on April 16, 2021 to obtain comments from the public and affected agencies. CDC received two comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) 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;

(b) Evaluate the accuracy of the agencies 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;

(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; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments (CDC–RFA–PS21–2103)—New—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

In 2021, CDC is implementing activities under a new cooperative agreement Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments (CDC–RFA–PS21–2103). Tools exist to prevent new cases of hepatitis A, hepatitis B, and hepatitis C, to treat people living with hepatitis B, and to cure people living with hepatitis C. Yet, new cases of viral hepatitis (VH) continue to rise, many people infected with VH remain undiagnosed, and far too many VH-related deaths occur in the US each year. The purpose of the activities under this new cooperative agreement is to enable states to collect data to evaluate disease burden and trends, and to analyze and disseminate that data to develop or refine recommendations, policies, and practices that will ultimately reduce the burden of VH in their jurisdictions. The goals of the activities are to reduce new VH infections, VH-related morbidity and mortality, and VH-related disparities, and to establish comprehensive national VH surveillance, which are in accordance with the Division of Viral Hepatitis 2025 Strategic Plan.

The activities of the new cooperative agreement are divided into two components (Component 1: Surveillance, and Component 2: Prevention), containing six strategies: 1.1, develop, implement, and maintain a plan to rapidly detect and respond to outbreaks for hepatitis A, B, and C; 1.2, collect, analyze, interpret, and disseminate data to characterize trends, and implement public health interventions for hepatitis A, acute hepatitis B and acute and chronic hepatitis C; 1.3 (contingent on available funding), collect, analyze, interpret, and disseminate data to characterize trends and implement public health interventions for chronic hepatitis B and perinatal hepatitis C; 2.1, support VH elimination planning and surveillance, and maximize access to testing, treatment, and prevention; 2.2 (contingent on available funding), increase access to HCV and HBV testing and referral to care in high-impact settings; and 2.3 (contingent on available funding), improve access to services preventing VH among persons who inject drugs. Contingent on funding, an optional component (Component 3: Special Projects) will support improved access to prevention, diagnosis, and treatment of viral, bacterial and fungal infections related to drug use in settings disproportionately affected by drug use.

Viral hepatitis case surveillance data will be collected per each jurisdiction's usual mechanism using variables that have been approved by OMB separately (OMB Control No. 0920–0728). Performance measures will be monitored to assess recipient performance, including quality of data, effective program implementation, and accountability of funds. Data collection via the Annual Performance Report will be used for program accountability and to inform performance improvement. Outbreak reporting will also be submitted throughout the year. These data, which complement case data as another key component of national viral hepatitis surveillance, are critical to determining both the level of viral hepatitis activity within a jurisdiction as well as the effectiveness of each jurisdiction's approach to cluster and outbreak response.

CDC requests approval for an estimated 240 annual burden hours. There is no cost to respondents other than their time.

Estimated Annualized Burden Hours

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Health Departments	APR: Component 1	59	1	1
Health Departments	APR: Component 2	59	1	1
Health Departments	APR: Component 3	14	1	1
Health Departments	Initial Outbreak Report Form	59	2	20/60
Health Departments	Outbreak Summary Report Form	59	2	20/60
Health Departments	Acute Viral Hepatitis Case Reporting	59	1	30/60

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–16377 Filed 7–30–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–21–1235 Docket No. CDC–2021–0076]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a continued information collection project titled ''Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth.'' This is a generic information collection package that supports qualitative and quantitative data collection from adolescents (ages 11–19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services designed to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

DATES: CDC must receive written comments on or before October 1, 2021.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0076 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *Regulations.gov*.

Please note: Submit all comments through the Federal eRulemaking portal *regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329; phone: 404–639–7118; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

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;

4. Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Assessments to Inform Program Refinement for HIV, other STD, and Pregnancy Prevention among Middle and High-School Aged Youth (OMB Control No. 0920–1235, Exp. 05/31/2022)—Extension—National Center for HIV/AIDS, Viral Hepatitis, STD, TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Centers for Disease Control and Prevention (CDC) requests three-year OMB approval for the extension of a Generic information collection package (OMB Control No. #0920–1235, Exp. 05/31/2022) that supports collection of quantitative and qualitative information from adolescents (ages 11–19) and their parents/caregivers for the purpose of needs assessment and program refinement for programs and services to prevent HIV, other sexually transmitted diseases (STDs), and pregnancy among middle and high school aged adolescents.

NCHHSTP conducts behavioral and health service assessments and research projects as part of its response to the domestic HIV/AIDS epidemic, STD prevention, TB elimination and viral hepatitis control with national, state, and local partners. Adolescents are a population with specific developmental, health and social, and resource needs, and their health risk factors and access to health care are addressed as a primary mission by the Division of Adolescent and School Health (DASH), and adolescents are a population of interest for several other NCHHSTP divisions. The assessment and research conducted by NCHHSTP is one pillar upon which recommendations and guidelines are revised and updated. Recommendations and guidelines for adolescent sexual risk reduction require that foundation of scientific evidence. Assessment of programmatic practices for adolescents helps to assure effective and evidence-based sexual risk reduction practices and efficient use of resources. Such assessments also help to improve programs through better identification of strategies relevant to adolescents as a population as well as specific sub-groups of adolescents at highest risk for HIV and other STDs so that programs can be better tailored for them.

The information collection requests under this generic package are intended to allow for data collection with two types of respondents:

- Adolescents (11–19 years old) of middle and high school age; and
- Parents and/or caregivers of adolescents of middle and high school age. For the purposes of this generic package, parents/caregivers include the adult primary caregiver(s) for a child's basic needs (*e.g.,* food, shelter, and safety). This includes biological parents; other biological relatives such as grandparents, aunts, uncles, or siblings;

and non-biological parents such as adoptive, foster, or stepparents.

The types of information collection activities included in this generic package are:

(1) Quantitative data collection through electronic, telephone, or paper questionnaires to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age.

(2) Qualitative data collection through electronic, telephone, or paper means to gather information about programmatic and service activities related to the prevention of HIV and other STDs among adolescents of middle- and high-school age. Qualitative data collection may involve focus groups and in-depth interviewing through group interviews, and cognitive interviewing.

For adolescents, data collection instruments will include questions on demographic characteristics; experiences with programs and services to reduce the risk of HIV and other STD transmission; and knowledge, attitudes, behaviors, and skills related to sexual risk and protective factors on the individual, interpersonal, and community levels.

For parents and caregivers, data collection instruments will include questions on demographic characteristics as well as parents'/caregivers' (1) perceptions about programs and services provided to adolescents; (2) knowledge, attitudes, and perceptions about their adolescents' health risk and protective behaviors; and (3) parenting knowledge, attitudes, behaviors, and skills.

Any data collection request put forward under this generic clearance will identify the programs and/or services to be informed or refined, and will include a cross-walk of data elements to the aspects of the program the project team seeks to inform or refine. Because this request includes a wide range of possible data collection instruments, specific requests will include items of information to be collected and copies of data collection instruments. It is expected that all data collection instruments will be pilot-tested, and will be culturally, developmentally, and age appropriate for the adolescent populations included. Similarly, parent data collection instruments will be pilot-tested, and the data collection instruments will reflect the culture, developmental stage, and age of the parents' adolescent children. All data collection procedures will receive review and approval by an Institutional Review Board for the Protection of Human Subjects and follow appropriate consent and assent procedures as outlined in the IRB-approved protocols. These will be described in the individual information collection requests put forward under this Generic package.

The table below provides the estimated annualized response burden for up to 15 individual data collections per year under this generic clearance at 57,584 hours. Participation of respondents is voluntary. There is no cost to participants other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Middle and High School Age Adolescents.	Youth Questionnaire	20,000	1	50/60	16,667
Middle and High School Age Adolescents.	Pre/Post youth questionnaire	10,000	2	50/60	16,667
Middle and High School Age Adolescents.	Youth interview/focus group guide	3,000	2	90/60	9,000
Parents/caregivers of adolescents	Parent/Caregiver questionnaire	7,500	2	25/60	6,250
Parents/caregivers of adolescents	Parent/Caregiver interview/focus group guide.	3,000	2	90/60	9,000
Total					57,584

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2021–16376 Filed 7–30–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0758]

Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Antimicrobial Drugs Advisory Committee. The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on October 7, 2021, from 9 a.m. to 5 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of this COVID–19 pandemic, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2021–N–0758. The docket will close on October 6, 2021. Submit either electronic or written comments on this public meeting by October 6, 2021. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 6, 2021. The *https://www.regulations.gov* electronic filing

system will accept comments until 11:59 p.m. Eastern Time at the end of October 6, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Comments received on or before September 23, 2021, will be provided to the committee. Comments received after that date will be taken into consideration by FDA. In the event that the meeting is cancelled, FDA will continue to evaluate any relevant applications or information, and consider any comments submitted to the docket, as appropriate.

You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–N–0758 for ''Antimicrobial Drugs Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' FDA will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify the information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT:

Moon Hee V. Choi, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–2894, Fax: 301–847–8533, email: *AMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at *https://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. The committee will discuss new drug application (NDA) 215596, for maribavir oral tablets, submitted by Takeda Pharmaceuticals USA, Inc., for the treatment of adults with post-transplant cytomegalovirus infection and/or disease, including infections resistant and/or refractory to ganciclovir, valganciclovir, cidofovir, or foscarnet.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available on FDA's website at the time of the advisory committee meeting. Background material and the link to the online teleconference meeting room will be available at *https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before September 23, 2021, will be provided to the committee. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of

proposed participants, and an indication of the approximate time requested to make their presentation on or before September 15, 2021. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by September 16, 2021.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Moon Hee V. Choi (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16356 Filed 7–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–0659]

Medical Device User Fee Rates for Fiscal Year 2022

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2022. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2022, which apply from October 1, 2021, through September 30, 2022, and provides information on how the fees for FY 2022 were determined, the payment procedures you should follow, and how you may qualify for reduced small business fees.

FOR FURTHER INFORMATION CONTACT:

For information on Medical Device User Fees: https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa.

For questions relating to the MDUFA Small Business Program, please visit the Center for Devices and Radiological Health's website: https://www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program.

For questions relating to this notice: Andrew Bank, Office of Financial Management, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 62019A, Beltsville, MD 20705, 301–796–0292.

SUPPLEMENTARY INFORMATION:

I. Background

Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests (for simplicity, this document refers to these collectively as ''submissions'' or ''applications''); for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee (see 21 U.S.C. 379j(d) and (e)).

Under the FD&C Act, the fee rate for each type of submission is set at a specified percentage of the standard fee for a premarket application (a premarket application is a premarket approval application (PMA), a product development protocol (PDP), or a biologics license application (BLA)). The FD&C Act specifies the base fee for a premarket application for each year from FY 2018 through FY 2022; the base fee for a premarket application received by FDA during FY 2022 is $329,000. From this starting point, this document establishes FY 2022 fee rates for certain types of submissions, and for periodic reporting, by applying criteria specified in the FD&C Act.

The FD&C Act specifies the base fee for establishment registration for each year from FY 2018 through FY 2022; the base fee for an establishment registration in FY 2022 is $4,978. There is no reduction in the registration fee for small businesses. Each establishment that is registered (or is required to register) with the Secretary of Health and Human Services under section 510 of the FD&C Act (21 U.S.C. 360) because such establishment is engaged in the manufacture, preparation, propagation, compounding, or processing of a device is required to pay the annual fee for establishment registration.

II. Revenue Amount for FY 2022

The total revenue amount for FY 2022 is $213,687,660, as set forth in the statute prior to the inflation adjustment (see 21 U.S.C. 379j(b)(3)). MDUFA directs FDA to use the yearly total revenue amount as a starting point to set the standard fee rates for each fee type. The fee calculations for FY 2022 are described in this document.

Inflation Adjustment

MDUFA specifies that the $213,687,660 is to be adjusted for inflation increases for FY 2022 using two separate adjustments—one for payroll costs and one for non-payroll costs (see 21 U.S.C. 379j(c)(2)). The base inflation adjustment for FY 2022 is the sum of one plus the two separate adjustments and is compounded as specified in the statute (see 21 U.S.C. 379j(c)(2)(C) and 379j(c)(2)(B)).

The component of the inflation adjustment for payroll costs is the average annual percent change in the cost of all personnel compensation and benefits (PC&B) paid per full-time equivalent position (FTE) at FDA for the first 3 of the 4 preceding FYs, multiplied by 0.60, or 60 percent (see 21 U.S.C. 379j(c)(2)(C)).

Table 1 summarizes the actual cost and FTE data for the specified FYs, and provides the percent change from the previous FY and the average percent change over the first 3 of the 4 FYs preceding FY 2022. The 3-year average is 2.7383 percent (rounded).

TABLE 1—FDA PC&BS EACH YEAR AND PERCENT CHANGE

Fiscal year	2018	2019	2020	3-Year average
Total PC&B	$2,690,678,000	$2,620,052,000	$2,875,592,000	
Total FTE	17,023	17,144	17,535	
PC&B per FTE	$158,061	$152,826	$163,992	
Percent change from previous year	4.2206%	−3.3120%	7.3063%	2.7383%

The payroll adjustment is 2.7383 percent multiplied by 60 percent, or 1.6430 percent. The statute specifies that the component of the inflation adjustment for non-payroll costs for FY 2022 is the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-VA-WV; Not Seasonally Adjusted; All Items; Annual Index) for the first 3 of the preceding 4 years of available data multiplied by 0.40, or 40 percent (see 21 U.S.C. 379j(c)(2)(C)). As a result of a geographical revision made by the Bureau of Labor and Statistics in January 2018,[1] the ''Washington-Baltimore, DC-MD-VA-WV'' index was discontinued and replaced with two separate indices (*i.e.,* ''Washington-Arlington-Alexandria, DC-VA-MD-WV'' and ''Baltimore-Columbia-Towson, MD''). In order to continue applying a CPI that best reflects the geographic region in which FDA is headquartered and that provides the most current data available, the Washington-Arlington-Alexandria index has been used since FY 2020 and will be used in calculating the relevant adjustment factors for FY 2022 and subsequent years.

Table 2 provides the summary data and the 3-year average percent change in the specified CPI for the Washington-Arlington-Alexandria area. These data are published by the Bureau of Labor Statistics and can be found on their website under series Id CUURS35ASA0 at: *https://data.bls.gov/pdq/SurveyOutputServlet?data_tool=dropmap&series_id=CUURS35ASA0,CUUSS35ASA0.*

TABLE 2—ANNUAL AND 3-YEAR AVERAGE PERCENT CHANGE IN WASHINGTON-ARLINGTON-ALEXANDRIA AREA CPI

Fiscal year	2018	2019	2020	3-Year average
Annual CPI	261.445	264.777	267.157	
Annual Percent Change	2.0389%	1.2745%	0.8989%	
3-Year Average Percent Change in CPI				1.4041%

The non-payroll adjustment is 1.4041 percent multiplied by 40 percent, or 0.5616 percent. Next, the payroll adjustment (1.6430 percent or 0.016430) is added to the non-payroll adjustment (0.5616 percent or .005616), for a total of 2.2046 percent (or 0.022046). To complete the inflation adjustment, 1 (100 percent or 1.0) is added for a total base inflation adjustment of 1.022046 for FY 2022.

MDUFA IV provides for this inflation adjustment to be compounded for FY 2022 and each subsequent fiscal year (see 21 U.S.C. 379j(c)(2)(B)(ii)). To complete the compounded inflation adjustment for FY 2022, the FY 2021 compounded adjustment (1.114808) is multiplied by the FY 2022 base inflation adjustment (1.022046) to reach the applicable inflation adjustment of 1.139385 (rounded) for FY 2022. We then multiply the total revenue amount for FY 2022 ($213,687,660) by 1.139385, yielding an inflation adjusted total revenue amount of $243,473,000 (rounded to the nearest thousand dollars).

III. Fees for FY 2022

Under the FD&C Act, all submission fees and the periodic reporting fee are set as a percent of the standard (full) fee for a premarket application (see 21 U.S.C. 379j(a)(2)(A)).

A. Inflation Adjustment

MDUFA specifies that the base fees of $329,000 (premarket application) and $4,978 (establishment registration) are to be adjusted for FY 2022 using the same methodology as that for the total revenue inflation adjustment in section II (see 21 U.S.C. 379j(c)(2)(D)(i)). Multiplying the base fees by the compounded inflation adjustment of 1.139385 yields inflation adjusted base fees of $374,858 (premarket application) and $5,672 (establishment registration).

B. Further Adjustments

After the applicable inflation adjustment to fees is done, FDA may increase, if necessary to achieve the inflation adjusted total revenue amount, the base fee amounts on a uniform proportionate basis (see 21 U.S.C. 379j(c)(2)(D)(ii)). If necessary, after this adjustment, FDA may further increase the base establishment registration fees to generate the inflation adjusted total revenue amount (see 21 U.S.C. 379j(c)(3)).

C. Calculation of Fee Rates

Table 3 provides the last 3 years of fee-paying submission counts and the 3-year average. These numbers are used to project the fee-paying submission counts that FDA will receive in FY 2022.

TABLE 3—THREE-YEAR AVERAGE OF FEE-PAYING SUBMISSIONS

Application type	FY 2018 actual	FY 2019 actual	FY 2020 actual	3-Year average
Full Fee Applications	38	32	30	33
Small Business	7	8	6	7
Panel-Track Supplement	23	14	22	20

[1] The Bureau of Labor Statistics' Announcement of the geographical revision can be viewed at *https://www.bls.gov/cpi/additional-resources/geographic-revision-2018.htm.*

TABLE 3—THREE-YEAR AVERAGE OF FEE-PAYING SUBMISSIONS—Continued

Application type	FY 2018 actual	FY 2019 actual	FY 2020 actual	3-Year average
Small Business	5	4	6	5
De Novo Classification Request	27	12	11	17
Small Business	29	37	18	28
180-Day Supplements	133	124	126	128
Small Business	27	23	21	24
Real-Time Supplements	169	213	175	186
Small Business	34	43	29	35
510(k)s	2,122	2,069	2,049	2,080
Small Business	1,385	1,558	1,667	1,537
30-Day Notice	1,058	925	867	950
Small Business	98	111	105	105
513(g) (21 U.S.C. 360c(g)) Request for Classification Information	84	75	96	85
Small Business	33	54	57	48
Annual Fee for Periodic Reporting	624	629	420	558
Small Business [2]	74	96	68	79
Establishment Registration	27,544	27,734	41,409	32,229

The information in table 3 is necessary to estimate the amount of revenue that will be collected based on the fee amounts. Table 4 displays the FY 2022 base fees set in statute (column one) and the inflation adjusted base fees (per calculations in section III.A.) (column two). Using the inflation adjusted fees and the 3-year averages of fee-paying submissions, collections are projected to total $262,694,460, which is $19,221,460 higher than the inflation adjusted total revenue amount (in section II). The fees in column two are those we are establishing in FY 2022, which are the standard fees.

TABLE 4—FEES NEEDED TO ACHIEVE NEW FY 2022 REVENUE TARGET

Application type	FY 2022 statutory fees (base fees)	FY 2022 Inflation adjusted statutory base fees (standard fees)	3-Year average of fee-paying submissions	FY 2022 revenue from adjusted fees
Full Fee Applications	$329,000	$374,858	33	$12,370,303
Small Business	82,250	93,714	7	656,001
Panel-Track Supplement	246,750	281,143	20	5,622,865
Small Business	61,688	70,286	5	351,429
De Novo Classification Request	98,700	112,457	17	1,911,774
Small Business	24,675	28,114	28	787,201
180-Day Supplements	49,350	56,229	128	7,197,267
Small Business	12,338	14,057	24	337,372
Real-Time Supplements	23,030	26,240	186	4,880,647
Small Business	5,758	6,560	35	229,600
510(k)s	11,186	12,745	2,080	26,509,934
Small Business	2,797	3,186	1,537	4,897,328
30-Day Notice	5,264	5,998	950	5,697,837
Small Business	2,632	2,999	105	314,880
513(g) Request for Classification Information	4,442	5,061	85	430,149
Small Business	2,221	2,530	48	121,454
Annual Fee for Periodic Reporting	11,515	13,120	558	7,320,970
Small Business	2,879	3,280	79	259,120
Establishment Registration	4,978	5,672	32,229	182,798,329
Total				262,694,460

The standard fee (adjusted base amount) for a premarket application, including a BLA, and for a premarket report and a BLA efficacy supplement, is $374,858 for FY 2022. The fees set by reference to the standard fee for a premarket application are:

- For a panel-track supplement, 75 percent of the standard fee;
- For a de novo classification request, 30 percent of the standard fee;
- For a 180-day supplement, 15 percent of the standard fee;
- For a real-time supplement, 7 percent of the standard fee;
- For an annual fee for periodic reporting concerning a class III device, 3.5 percent of the standard fee;
- For a 510(k) premarket notification, 3.4 percent of the standard fee;
- For a 30-day notice, 1.6 percent of the standard fee; and
- For a 513(g) request for classification information, 1.35 percent of the standard fee.

For all submissions other than a 30-day notice and a 513(g) request for classification information, the small business fee is 25 percent of the standard (full) fee for the submission (see 21 U.S.C. 379j(d)(2)(C) and (e)(2)(C)). For a 30-day notice and a 513(g) request for classification information, the small business fee is 50

percent of the standard (full) fee for the submission (see 21 U.S.C. 379j(d)(2)(C)).

The annual fee for establishment registration, after adjustment, is set at $5,672 for FY 2022. There is no small business rate for the annual establishment registration fee; all establishments pay the same fee.

Table 5 summarizes the FY 2022 rates for all medical device fees.

TABLE 5—MEDICAL DEVICE FEES FOR FY 2022

Application fee type	Standard fee (as a percent of the standard fee for a premarket application)	FY 2022 standard fee	FY 2022 small business fee
Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act, or a BLA submitted under section 351 of the Public Health Service Act (the PHS Act) (42 U.S.C. 262)).	Base fee specified in statute ..	$374,858	$93,714
Premarket report (submitted under section 515(c)(2) of the FD&C Act)	100	374,858	93,714
Efficacy supplement (to an approved BLA under section 351 of the PHS Act)	100	374,858	93,714
Panel-track supplement	75	281,143	70,286
De novo classification request	30	112,457	28,114
180-day supplement	15	56,229	14,057
Real-time supplement	7	26,240	6,560
510(k) premarket notification submission	3.40	12,745	3,186
30-day notice	1.60	5,998	2,999
513(g) request for classification information	1.35	5,061	2,530
Annual Fee Type			
Annual fee for periodic reporting on a class III device	3.50	13,120	3,280
Annual establishment registration fee (to be paid by the establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device, as defined by 21 U.S.C. 379i(14)).	Base fee specified in statute ..	5,672	5,672

IV. How To Qualify as a Small Business for Purposes of Medical Device Fees

If your business, including your affiliates, has gross receipts or sales of no more than $100 million for the most recent tax year, you may qualify for reduced small business fees. If your business, including your affiliates, has gross sales or receipts of no more than $30 million, you may also qualify for a waiver of the fee for your first premarket application (*i.e.* PMA, PDP, or BLA) or premarket report. If you want to pay the small business fee rate for a submission or you want to receive a waiver of the fee for your first premarket application or premarket report, you should submit the materials showing you qualify as a small business at least 60 days before you send your submission to FDA. Please note that the establishment registration fee is not eligible for a reduced small business fee. As a result, if the establishment registration fee is the only medical device user fee that you will pay in FY 2022, you should not submit a Small Business Certification Request. FDA will review your information and determine whether you qualify as a small business eligible for the reduced fee and/or fee waiver. If you make a submission before FDA finds that you qualify as a small business, you must pay the standard (full) fee for that submission.

If your business qualified as a small business for FY 2021, your status as a small business will expire at the close of business on September 30, 2021. You must re-qualify for FY 2022 in order to pay small business fees during FY 2022.

A. Domestic (U.S.) Businesses

If you are a domestic (U.S.) business and wish to qualify as a small business for FY 2022, submit the following to FDA:

1. A completed MDUFA Small Business Certification Request For a Business Headquartered in the United States (Form FDA 3602). Form FDA 3602 is provided in the FDA Forms database: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573420.pdf.*

2. A signed copy of your Federal (U.S.) Income Tax Return for the most recent tax year. The most recent tax year will be 2021, except:

If you submit your MDUFA Small Business Certification Request for FY 2022 before April 15, 2022, and you have not yet filed your return for 2021, you may use tax year 2020.

If you submit your MDUFA Small Business Certification Request for FY 2022 on or after April 15, 2022, and have not yet filed your 2021 return because you obtained an extension, you may submit your most recent return filed prior to the extension.

3. For each of your affiliates, either:

- If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year, or
- If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the business has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

B. Foreign Businesses

If you are a foreign business, and wish to qualify as a small business for FY 2022, submit the following:

1. A completed MDUFA Foreign Small Business Certification Request For a Business Headquartered Outside the United States (Form FDA 3602A). Form FDA 3602A is provided in the FDA Forms database: *https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM573423.pdf.*

2. A National Taxing Authority Certification, completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates of the gross receipts or sales collected.

3. For each of your affiliates, either:

• If the affiliate is a domestic (U.S.) business, a signed copy of the affiliate's Federal (U.S.) Income Tax Return for the most recent tax year (2021 or later), or

• If the affiliate is a foreign business and cannot submit a Federal (U.S.) Income Tax Return, a National Taxing Authority Certification completed by, and bearing the official seal of, the National Taxing Authority of the country in which the firm is headquartered. The National Taxing Authority is the foreign equivalent of the U.S. Internal Revenue Service. This certification must show the amount of gross receipts or sales for the most recent tax year, in both U.S. dollars and the local currency of the country, the exchange rate used in converting the local currency to U.S. dollars, and the dates for the gross receipts or sales collected. The business must also submit a statement signed by the head of the business's firm or by its chief financial officer that the applicant has submitted certifications for all of its affiliates, identifying the name of each affiliate, or that the business has no affiliates.

V. Procedures for Paying Application Fees

If your application or submission is subject to a fee and your payment is received by FDA between October 1, 2021, and September 30, 2022, you must pay the fee in effect for FY 2022. To avoid delay in the review of your application, you should pay the application fee before or at the time you submit your application to FDA. The later of the date that the application is received in the reviewing center's document room or the date the U.S. Treasury recognizes the payment determines whether the fee rates for FY 2021 or FY 2022 apply. FDA must receive the correct fee at the time that an application is submitted, or the application will not be accepted for filing or review.

FDA requests that you follow the steps below before submitting a medical device application subject to a fee to ensure that FDA links the fee with the correct application. (Note: Do not send your user fee check to FDA with the application.)

A. Secure a Payment Identification Number (PIN) and Medical Device User Fee Cover Sheet From FDA Before Submitting Either the Application or the Payment

Log into the User Fee System at: *https://userfees.fda.gov/OA_HTML/mdufmaCAcdLogin.jsp.* Complete the Medical Device User Fee cover sheet. Be sure you choose the correct application submission date range. (Two choices will be offered until October 1, 2021. One choice is for applications and fees that will be received on or before September 30, 2021, which are subject to FY 2021 fee rates. A second choice is for applications and fees received on or after October 1, 2021, which are subject to FY 2022 fee rates.) After completing data entry, print a copy of the Medical Device User Fee cover sheet and note the unique PIN located in the upper right-hand corner of the printed cover sheet.

B. Electronically Transmit a Copy of the Printed Cover Sheet With the PIN

When you are satisfied that the data on the cover sheet is accurate, electronically transmit that data to FDA according to instructions on the screen. Applicants are required to set up a user account and password to assure data security in the creation and electronic submission of cover sheets.

C. Submit Payment for the Completed Medical Device User Fee Cover Sheet

1. The preferred payment method is online using electronic check (Automated Clearing House (ACH) also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). FDA has partnered with the U.S. Department of the Treasury to utilize *Pay.gov,* a web-based payment system, for online electronic payment. You may make a payment via electronic check or credit card after submitting your cover sheet. Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* Note: only full payments are accepted. No partial payments can be made online. Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S bank accounts as well as U.S. credit cards.

2. If paying with a paper check:

• All paper checks must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.

• Please write your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) on your check.

• Mail the paper check and a copy of the completed cover sheet to: Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

If you prefer to send a check by a courier, the courier may deliver the check to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

3. If paying with a wire transfer:

• Please include your application's unique PIN (from the upper right-hand corner of your completed Medical Device User Fee cover sheet) in your wire transfer. Without the PIN, your payment may not be applied to your cover sheet and review of your application may be delayed.

• The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

FDA records the official application receipt date as the later of the following: (1) The date the application was received by the FDA Document Control Center for the reviewing Center or (2) the date the U.S. Treasury recognizes the payment. It is helpful if the fee arrives at the bank at least 1 day before the application arrives at FDA.

D. Submit Your Application to FDA With a Copy of the Completed Medical Device User Fee Cover Sheet

Please submit your application and a copy of the completed Medical Device User Fee cover sheet to the address located at *https://www.fda.gov/cdrhsubmissionaddress.*

VI. Procedures for Paying the Annual Fee for Periodic Reporting

You will be invoiced at the end of the quarter in which your PMA Periodic Report is due. Invoices will be sent based on the details included on your PMA file. You are responsible for ensuring FDA has your current billing information, and you may update your contact information for the PMA by submitting an amendment to the pending PMA or a supplement to the approved PMA.

1. The preferred payment method is online using electronic check (ACH also known as eCheck) or credit card (Discover, VISA, MasterCard, American Express). Secure electronic payments can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay* (Note: only full payments are accepted. No partial payments can be made online). Once you search for your invoice, select ''Pay Now'' to be redirected to *Pay.gov.* Note that electronic payment options are based on the balance due. Payment by credit card is available for balances that are less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

2. If paying with a paper check:

The check must be in U.S. currency from a U.S. bank and made payable to the Food and Drug Administration. If needed, FDA's tax identification number is 53–0196965.

- Please write your invoice number on the check.
- *Mail the paper check and a copy of the invoice to:* Food and Drug Administration, P.O. Box 979033, St. Louis, MO 63197–9000. (Please note that this address is for payments of application and annual report fees only and is not to be used for payment of annual establishment registration fees.)

To send a check by a courier, the courier must deliver the check and printed copy of the cover sheet to: U.S. Bank, Attn: Government Lockbox 979033, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery).

3. When paying by a wire transfer, it is required that the invoice number is included; without the invoice number the payment may not be applied. If the payment amount is not applied, the invoice amount would be referred to collections. The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full.

Use the following account information when sending a wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33.

VII. Procedures for Paying Annual Establishment Registration Fees

To pay the annual establishment registration fee, firms must access the Device Facility User Fee (DFUF) website at *https://userfees.fda.gov/OA_HTML/furls.jsp.* (FDA has verified the website address, but FDA is not responsible for any subsequent changes to the website address after this document publishes in the **Federal Register**.) Create a DFUF order and you will be issued a PIN when you place your order. After payment has been processed, you will be issued a payment confirmation number (PCN). You will not be able to register your establishment if you do not have a PIN and a PCN. An establishment required to pay an annual establishment registration fee is not legally registered in FY 2022 until it has completed the steps below to register and pay any applicable fee (see 21 U.S.C. 379j(f)(2)).

Companies that do not manufacture any product other than a licensed biologic are required to register in the Blood Establishment Registration (BER) system. FDA's Center for Biologics Evaluation and Research (CBER) will send establishment registration fee invoices annually to these companies.

A. Submit a DFUF Order With a PIN From FDA Before Registering or Submitting Payment

To submit a DFUF Order, you must create or have previously created a user account and password for the user fee website listed previously in this section. After creating a user name and password, log into the Establishment Registration User Fee FY 2022 store. Complete the DFUF order by entering the number of establishments you are registering that require payment. When you are satisfied that the information in the order is accurate, electronically transmit that data to FDA according to instructions on the screen. Print a copy of the final DFUF order and note the unique PIN located in the upper right-hand corner of the printed order.

B. Pay for Your DFUF Order

Unless paying by U.S. credit card, all payments must be in U. S. currency and drawn on a U.S. bank.

1. If paying by credit card or electronic check (ACH or eCheck):

The DFUF order will include payment information, including details on how you can pay online using a credit card or electronic check. Follow the instructions provided to make an electronic payment.

2. If paying with a paper check:

The check must be in U.S. currency and drawn on a U.S. bank, and mailed to: Food and Drug Administration, P.O. Box 979108, St. Louis, MO 63197–9000. (Note: This address is different from the address for payments of application and annual report fees and is to be used only for payment of annual establishment registration fees.)

If a check is sent by a courier that requests a street address, the courier can deliver the check to: U.S. Bank, Attn: Government Lockbox 979108, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This U.S. Bank address is for courier delivery only. If you have any questions concerning courier delivery, contact U.S. Bank at 314–418–4013. This telephone number is only for questions about courier delivery.)

Please make sure that both of the following are written on your check: (1) The FDA post office box number (P.O. Box 979108) and (2) the PIN that is printed on your order. Include a copy of your printed order when you mail your check.

3. If paying with a wire transfer:

Wire transfers may also be used to pay annual establishment registration fees. To send a wire transfer, please read and comply with the following information:

Include your order's unique PIN (in the upper right-hand corner of your completed DFUF order) in your wire transfer. Without the PIN, your payment may not be applied to your facility and your registration may be delayed.

The originating financial institution may charge a wire transfer fee. If the financial institution charges a wire transfer fee, it is required that you add that amount to the payment to ensure that the invoice is paid in full. Use the following account information when sending a wire transfer: U.S. Dept. of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Acct. No. 75060099, Routing No. 021030004, SWIFT: FRNYUS33. If needed, FDA's tax identification number is 53–0196965.

C. Complete the Information Online To Update Your Establishment's Annual Registration for FY 2022, or To Register a New Establishment for FY 2022

Go to the Center for Devices and Radiological Health's website at *https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing* and click the ''Access Electronic Registration'' link on the left side of the page. This opens up a new page with important information about the FDA Unified Registration and Listing System (FURLS). After reading this information, click on the ''Access Electronic Registration'' link in the middle of the page. This link takes you to an FDA Industry Systems page with tutorials that demonstrate how to create a new FURLS user account, if your establishment did not create an account in FY 2021. Manufacturers of licensed biologics should register in the BER system at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-establishment-registration.*

Enter your existing account ID and password to log into FURLS. From the FURLS/FDA Industry Systems menu, click on the Device Registration and Listing Module (DRLM) of FURLS button. New establishments will need to register and existing establishments will update their annual registration using choices on the DRLM menu. When you choose to register or update your annual registration, the system will prompt you through the entry of information about your establishment and your devices. If you have any problems with this process, email: *reglist@cdrh.fda.gov* or call 301–796–7400 for assistance. (Note: This email address and this telephone number are for assistance with establishment registration only; they are not to be used for questions related to other aspects of medical device user fees.) Problems with the BER system should be directed to *https://www.accessdata.fda.gov/scripts/email/cber/bldregcontact.cfm* or call 240–402–8360.

D. Enter Your DFUF Order PIN and PCN

After completing your annual or initial registration and device listing, you will be prompted to enter your DFUF order PIN and PCN, when applicable. This process does not apply to establishments engaged only in the manufacture, preparation, propagation, compounding, or processing of licensed biologic devices. CBER will send invoices for payment of the establishment registration fee to such establishments.

Dated: July 28, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16408 Filed 7–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0658]

Vithal K. Patel; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying a request for a hearing submitted by Vithal K. Patel (Mr. Patel) and issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Mr. Patel for 1 year from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Mr. Patel was convicted of conspiracy to commit a felony under Federal law for conduct relating to the regulation of drug products under the FD&C Act and that the type of conduct underlying the conviction undermined the process for the regulation of drugs. In determining the appropriateness and period of Mr. Patel's debarment, FDA considered the relevant factors listed in the FD&C Act. Mr. Patel has failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable August 2, 2021.

ADDRESSES: Any application for termination of debarment by Mr. Patel under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2011–N–0658. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed

except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT: Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(II) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(II)) permits FDA to debar an individual if it finds: (1) That the individual has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of any drug product under the FD&C Act and (2) that the type of conduct serving as the basis of the conviction undermines the process for the regulation of drugs.

On August 7, 2007, Mr. Patel pled guilty to a felony count of conspiracy to distribute misbranded and adulterated drugs in violation of 18 U.S.C. 371. On December 16, 2010, the U.S. District Court for the District of New Jersey entered the conviction, sentenced Mr. Patel to 2 years of probation, and imposed a $3,000 fine. Mr. Patel's conviction stemmed from his employment at Able Laboratories, Inc. (Able), where he was a Research and Development Manager and later the Associate Director for Technical Service. Mr. Patel and others conspired to cause the introduction of misbranded and adulterated drugs into interstate commerce with the intent to defraud and mislead the United States, in violation of sections 301(a) and 303(a)(2) of the FD&C Act (21 U.S.C. 331(a) and 333(a)(2)). According to the criminal information to which he pled guilty under a plea agreement, Mr. Patel and his coconspirators agreed to violate FDA's regulations regarding good manufacturing practice for drugs by, among other things, manipulating and falsifying testing data and information. Mr. Patel specifically admitted to an overt act in furtherance of the conspiracy, namely supervising the manipulation of the process for manufacturing promethazine, a prescription antihistamine medication.

By letter dated January 6, 2012, FDA's Office of Regulatory Affairs (ORA) notified Mr. Patel of an opportunity for a hearing on a proposal to debar him for 5 years from providing services in any capacity to a person having an approved or pending drug product application. In its proposal, ORA concluded that Mr. Patel should be debarred for 5 years based on four applicable considerations in section 306(c)(3) of the FD&C Act: (1) The nature and seriousness of his offense, (2) the nature and extent of management participation in the offense, (3) the nature and extent of voluntary steps taken to mitigate the impact on the public, and (4) prior convictions involving matters within FDA's jurisdiction. ORA found that the first three of those considerations weigh in favor of debarment and noted, as to the fourth consideration, that FDA is unaware of any prior convictions.

In a letter dated March 8, 2012, Mr. Patel requested a hearing on the proposal and submitted materials and arguments in support of his request. In his submission, Mr. Patel acknowledges his conviction of a conspiracy to commit a felony under Federal law and does not dispute that the conduct underlying that conviction related to the regulation of a drug product or that conduct of that type undermines the process for the regulation of drugs. He argues, however, that with respect to the considerations for determining the appropriateness and period of debarment under section 306(c)(3) of the FD&C Act, there are genuine and substantial issues of fact for resolution at a hearing.

II. Statutory and Regulatory Framework Regarding Part 12 Hearings

Under the authority delegated by the Commissioner of Food and Drugs, the Chief Scientist has considered Mr. Patel's submission. Under § 12.24(a)(2) (21 CFR 12.24(a)(2)), the Agency reviews a hearing request to determine whether a hearing is justified. FDA has the authority to deny a hearing when it appears from the hearing request that there are no material disputes of fact. See *Costle* v. *Pacific Legal Found.,* 445 U.S. 198, 214 (1980) (a party seeking a hearing is required to meet a ''threshold burden of tendering evidence suggesting the need for a hearing''), *reh'g denied,* 446 U.S. 947 (1980), citing *Weinberger* v. *Hynson, Westcott & Dunning, Inc.,* 412 U.S. 609, 620–21 (1973); *Pineapple Growers Ass'n* v. *FDA,* 673 F.2d 1083, 1085–86 (9th Cir. 1982) (holding that no hearing is necessary unless ''material issues of fact'' have been raised).

In determining whether there are material issues of fact suitable for a hearing, FDA considers the specific criteria set out in § 12.24(b) and grants a hearing only if the material submitted in support of the request shows the following: (1) There is a genuine and substantial factual issue for resolution at a hearing; a hearing will not be granted on issues of policy or law; (2) the factual issue can be resolved by available and specifically identified reliable evidence; a hearing will not be granted on the basis of mere allegations or denials or general descriptions of positions and contentions; (3) the data and information submitted, if established at a hearing, would be adequate to justify resolution of the factual issue in the way sought by the requestor; a hearing will be denied if the Agency concludes that the data and information submitted are insufficient to justify the factual determination urged, even if accurate; (4) resolution of the factual issue in the way sought by the person is adequate to justify the action requested; a hearing will not be granted on factual issues that are not determinative with respect to the action requested (*e.g.,* if the Agency concludes that the action would be the same even if the factual issue were resolved in the way sought); (5) the action requested is not inconsistent with any provision in the FD&C Act or any FDA regulation; and (6) the requirements in other applicable regulations, *e.g.,* 21 CFR 10.20, 12.21, and 12.22, and in the notice of an opportunity for hearing are met.

III. Arguments

In his request for a hearing, Mr. Patel challenges ORA's findings with respect to the three considerations that it concluded weighed in favor of his debarment. Mr. Patel also contends that there are two additional considerations under section 306(c)(3) of the FD&C Act that were not considered by ORA and should weigh in his favor against debarment. Section 306(c)(3) of the FD&C Act explicitly requires that FDA consider, ''where applicable,'' certain factors ''[i]n determining the appropriateness and the period of debarment'' for any permissive debarment.

A. Nature and Seriousness of the Offense

Regarding the nature and seriousness of his offense, Mr. Patel contends that, in reaching its conclusion regarding the nature and seriousness of his felony

offense, ORA failed to consider certain important facts. Specifically, Mr. Patel argues that the overt act underlying his conspiracy conviction—namely supervising manipulation of the process for manufacturing promethazine—involved merely failing to document or follow proper procedures for a nitrogen flush and ''posed no danger to the end users, the public at large, or coworkers at Able.'' He reasons that, ''as an inert gas, nitrogen could not possibly interact with the [promethazine hydrochloride] in any way.'' Mr. Patel maintains that this factor should therefore not have weighed in favor of his debarment. However, as part of his guilty plea, Mr. Patel admitted to conspiring to cause the introduction of misbranded and adulterated products into interstate commerce, with the intent to defraud and mislead the United States. Therefore, even assuming that Mr. Patel did not intend for his conduct to harm anyone, the offense to which Mr. Patel pled guilty remains serious and weighs in favor of debarment.

B. Nature and Extent of Management Participation in the Offense

As to the consideration addressing the nature and extent of management participation, Mr. Patel argues that ORA's analysis overlooks the nature and extent of Mr. Patel's management participation in the offense and reaches the conclusion that this factor is unfavorable ''simply because Mr. Patel was not an entry level worker.'' In fact, Mr. Patel insists that he ''never participated in the production of commercial products at Able Labs'' and, as such, ''exercised no 'management' authority in connection with the nitrogen flush'' and ''had no input into or control over Able Labs' 'corporate policies and practices' or 'institutional controls' with respect to production processes.'' To the contrary, Mr. Patel emphasizes that ''both the United States Attorney's Office and [the court] confirmed that Mr. Patel was acting on the order of his superior managers to observe the nitrogen flush and was in fear the he would be terminated if he refused.''

In the proposal to debar, ORA stated:

As a Research and Development Manager and Associate Director of Technical Service, you were responsible for supervising numerous chemists and technicians who manufactured test batches to ensure product safety and effectiveness. Your management position also entailed monitoring the chemists' compliance with GMPs, as required by FDA, and SOPs established by the company and ensuring compliance with Able's SOPs, including protocols for investigating, logging, and archiving any aberrant, deviant, or failing analytical laboratory results. As supervisor, you held a position of authority in which your conduct served as an example to other employees. Accordingly, the Agency will consider this an unfavorable factor.

Mr. Patel does not dispute that he was in a supervisory position at Able. Even assuming Mr. Patel reasonably feared termination related to the conspiracy he joined, Mr. Patel does not contest that he worked in a position of authority at Able and had the responsibilities outlined in ORA's proposal to debar him for 5 years. Therefore, Mr. Patel has failed to create an issue for hearing with respect to whether the nature and extent of his management participation in the offense should weigh against debarment.

C. Changes in Ownership, Management, or Operations

Next, Mr. Patel argues that ORA incorrectly failed to consider ''whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future,'' under section 306(c)(3)(D) of the FD&C Act. Mr. Patel states that an offense will not occur here in the future because ''Able Labs is now defunct'' and he ''voluntarily left the pharmaceutical industry in 2007.''

FDA must consider, where applicable, ''whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future.'' The considerations in section 306(c)(3) of the FD&C Act are not only for individuals but also for corporations, partnerships, and associations subject to permissive debarment. This consideration does not typically apply to individuals because individuals are incapable of changes in ownership or management and could only alter the current operations of a business enterprise in which they are currently engaged. Even assuming for the sake of argument that an individual could point to changes in his or her current business practices as an applicable consideration under section 306(c)(3) of the FD&C Act, Mr. Patel's contention that, because he voluntarily left the pharmaceutical industry he has provided reasonable assurances that he will not commit the offense again given the opportunity, fails to create a genuine and substantial issue of fact that warrants a hearing. Furthermore, given that this debarment proceeding focuses on Mr. Patel rather than Able, it is immaterial that Able Labs is no longer in business.

D. Abbreviated New Drug Applications (ANDAs)

Mr. Patel argues that ''whether the person to be debarred is able to present adequate evidence that current production of drugs subject to abbreviated drug applications and all pending abbreviated drug applications are free of fraud or material false statements'' under section 306(c)(3)(E) of the FD&C Act should be considered in his favor because the improper manufacturing procedures for which Mr. Patel was convicted ''had no relation to a drug application in any way.'' This factor is only relevant for persons that have an ANDA. Mr. Patel has not presented any evidence that he has any existing abbreviated drug applications for consideration in his own name, and thus, this factor is not relevant in determining the appropriateness and length of debarment and fails to create a genuine and substantial issue of fact that warrants a hearing.

E. Nature and Extent of Voluntary Steps To Mitigate

Lastly, under section 306(c)(3)(C) of the FD&C Act, in determining the appropriateness and period of debarment, FDA must consider, where applicable, ''the nature and extent of voluntary steps to mitigate the effect on the public,'' including whether the person took specified corrective actions after the criminal violation or fully cooperated with any investigations. In the proposal to debar, ORA concluded that Mr. Patel's ''failure to take voluntary steps to mitigate the offense [he] committed'' rendered this an unfavorable factor. ORA based this conclusion on the fact that ''FDA has no information demonstrating that [Mr. Patel] took any voluntary steps to mitigate the impact of [his] actions on the public.''

In his hearing request, Mr. Patel maintains that he did, in fact, take voluntary steps to mitigate the effect of his offense on the public, including ''full cooperation with any investigations'' under section 306(c)(3)(C) of the FD&C Act. In support, Mr. Patel submits a letter from an Assistant U.S. Attorney who participated in his prosecution and a transcript of his sentencing. Quoting this letter, Mr. Patel maintains that his cooperation enabled the Government to ''expand its investigation to other individuals and to develop a better understanding of the misbranding conspiracy at Able Labs'' and ''permitted the government to vet the information . . . received from other

individuals and to follow new leads.'' Furthermore, he adds that he provided valuable ''details about events and discussions demonstrating that Able Labs' management had made changes to drug protocols.'' He relies on these submissions to demonstrate not only that he cooperated with the government and contributed to the successful prosecution of others, including Able's top manager, but also that the government argued at his sentencing that he provided ''substantial assistance'' in those investigations and moved for a more lenient sentence on that basis. Mr. Patel's account of his cooperation and substantial assistance in the investigation is undisputed and supported by the transcript of his sentencing. Therefore, the nature and extent of the voluntary steps Mr. Patel took to mitigate the impact of his offense on the public under section 306(c)(3)(C) of the FD&C Act weigh in Mr. Patel's favor in determining the appropriateness and period of debarment.

Given the undisputed facts described above, and after considering the applicable factors listed in section 306(c)(3) of the FD&C Act, the Chief Scientist finds that Mr. Patel's conviction warrants a 1-year debarment period. It is undisputed that Mr. Patel pled guilty to a serious offense and that he participated in the offense as a supervisor. However, Mr. Patel took significant steps to mitigate the effect of his offense on the public, as described in the Assistant U.S. Attorney's letter, and he has no prior convictions. Particularly in light of FDA's strong public policy interest in encouraging cooperation with authorities engaged in investigating wrongdoing related to the Agency's regulation of drugs, as reflected in section 306(c)(3)(C) of the FD&C Act, the Chief Scientist has determined that a debarment period of only 1 year is appropriate in this case.

IV. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(II) of the FD&C Act and under authority delegated to her by the Commissioner of Food and Drugs, finds that: (1) Mr. Patel has been convicted of a conspiracy to commit a felony under Federal law for conduct relating to the regulation of a drug product under the FD&C Act and (2) that the conduct which served as the basis for the conviction undermines the process for the regulation of drugs. FDA has considered the applicable factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 1 year is appropriate.

As a result of the foregoing findings, Mr. Patel is debarred for 1 year from providing services in any capacity to a person with an approved or pending drug product application under sections 505, 512, or 802 of the FD&C Act (21 U.S.C. 355, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective August 2, 2021 (see 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Mr. Patel, in any capacity during his period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Mr. Patel, during his period of debarment, provides services in any capacity to a person with an approved or pending drug product application, he will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Mr. Patel during his period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: July 27, 2021.

Denise Hinton,

Chief Scientist.

[FR Doc. 2021–16350 Filed 7–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0198]

Belen G. Ngo; Denial of Hearing; Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is denying Belen G. Ngo's (Ms. Ngo's) request for a hearing and is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Ms. Ngo for 5 years from providing services in any capacity to a person that has an approved or pending drug product application. FDA bases this order on a finding that Ms. Ngo was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and that the type of conduct underlying the conviction undermines the process for the regulation of drugs. In determining the appropriateness and period of Ms. Ngo's debarment, FDA considered the relevant factors listed in the FD&C Act. Ms. Ngo failed to file with the Agency information and analyses sufficient to create a basis for a hearing concerning this action.

DATES: This order is applicable August 2, 2021.

ADDRESSES: Any application for termination of debarment by Ms. Ngo under section 306(d) of the FD&C Act (application) may be submitted as follows:

Electronic Submissions

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. An application submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your application will be made public, you are solely responsible for ensuring that your application does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your application, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an application with confidential information that you do not wish to be made available to the public, submit the application as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For a written/paper application submitted to the Dockets Management Staff, FDA will post your application, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All applications must include the Docket No. FDA–2012–N–0198. Received applications will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at

https://www.regulations.gov or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit an application with confidential information that you do not wish to be made publicly available, submit your application only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of your application. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your application and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852 between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500. Publicly available submissions may be seen in the docket.

FOR FURTHER INFORMATION CONTACT:

Rachael Vieder Linowes, Office of Scientific Integrity, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 1, Rm. 4206, Silver Spring, MD 20993, 240–402–5931.

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(2)(B)(i)(I) of the FD&C Act (21 U.S.C. 335a(b)(2)(B)(i)(I)) permits FDA to debar an individual if it finds that: (1) The individual was convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) that the type of conduct underlying the conviction undermines the process for the regulation of drugs.

On September 6, 2011, in the U.S. District Court for the Eastern District of Virginia, Ms. Ngo pled guilty to a misdemeanor violation of the FD&C Act, namely failing to maintain records required by section 505(i) of the FD&C Act (21 U.S.C. 355(i)) in violation of sections 301(e) and 303(a)(1) (21 U.S.C. 331(e) and 333(a)(1)). Ms. Ngo's conviction stemmed from her actions as a clinical research coordinator for the Norfolk Diagnostic Center, doing business as Sentara Medical Group (Sentara). Eli Lilly Corp. (Eli Lilly) initiated a clinical study to investigate the effectiveness of lispro insulin for the purpose of applying for FDA approval to market lispro insulin for the treatment of Type 2 diabetes. Eli Lilly entered into an agreement with Sentara to conduct the ispro insulin study, and Sentara agreed to maintain records in accordance with 21 CFR 312.62(a) and by extension, section 505(i) of the FD&C Act. Ms. Ngo was a clinical research coordinator for the lispro insulin study and responsible for maintaining and completing case report forms (CRFs), which are the official records that document volunteers' participation in the study and contain vital medical information related to the performance of the study drug. Ms. Ngo knowingly and repeatedly falsified CRFs.

By letter dated April 27, 2012, FDA's Office of Regulatory Affairs (ORA) notified Ms. Ngo of its proposal to debar her for 5 years from providing services in any capacity to a person having an approved or pending drug product application. The proposal explained that the proposed debarment period was based on her misdemeanor conviction and that the maximum debarment period is 5 years. ORA explained that her conduct relating to the clinical trial relates to the development and approval, including the process for development and approval, of drug products; therefore, she was subject to debarment under section 306(b)(2)(B)(i)(I) of the FD&C Act.

The proposal outlined findings regarding the three applicable factors ORA considered in determining the appropriateness and period of debarment, as provided in section 306(c)(3) of the FD&C Act. ORA consider the nature and seriousness of the offense and the nature and extent of voluntary steps to mitigate the effect on the public as unfavorable factors for Ms. Ngo and weighed these factors against the absence of prior convictions involving matters within FDA's jurisdiction. ORA concluded, ''Weighing all the factors, the Agency has determined that the unfavorable factors far outweigh the favorable factor, and therefore warrant the imposition of a five-year period of debarment in this case, the maximum possible period of debarment.''

By letters dated May 22 and 23, 2012, through counsel, Ms. Ngo requested a hearing on the proposal. In her request for a hearing, Ms. Ngo acknowledges her conviction under Federal law and does not question the Agency's authority to debar her upon the basis of that conviction. However, Ms. Ngo argues that she should only be subject to a 1-year debarment, rather than FDA's proposed 5-year debarment, based on the considerations for determining the appropriateness and period of debarment under section 306(c)(3) of the FD&C Act. Ms. Ngo also included specific arguments related to the considerations under section 306(c)(3) of the FD&C Act.

Under the authority delegated by the Commissioner of Food and Drugs, the Chief Scientist has considered Ms. Ngo's request for a hearing. Hearings are granted only if there is a genuine and substantial issue of fact. Hearings will not be granted on issues of policy or law, on mere allegations, denials, or general descriptions of positions and contentions, or on data and information insufficient to justify the factual determination urged (*see* 21 CFR 12.24(b)).

The Chief Scientist has considered Ms. Ngo's arguments and concluded that they are unpersuasive and fail to raise a genuine and substantial issue of fact requiring a hearing.

II. Arguments

In support of her hearing request, Ms. Ngo makes many statements seemingly related to the nature and seriousness of her offense. Ms. Ngo first argues that the prosecution's failure to pursue a felony conviction reflects its judgment that a misdemeanor conviction and the terms of her probation or supervised release, which included an agreement not to engage in clinical research during that period, are sufficient to protect the public health. Ms. Ngo next argues that her role was too small to have a significant effect on the study's results and that, because of her ''minimal role'' in providing data, the maximum debarment period is not appropriate. Ms. Ngo states that her study was discontinued and Eli Lilly did not use any of her information ''in a detrimental way.'' Ms. Ngo also alleges that ''[t]here is no evidence that her data affected the

studies or resulted in the production of the drugs affected by the fraud'' and that ''[t]he drugs produced were free of fraud and material false statements.'' Ms. Ngo then asserts that her lack of financial motive for conducting her offense weighs in her favor because ''the maximum period of debarment should be reserved for those who profit.''

In determining the period of Ms. Ngo's debarment, whether she could have been convicted of a felony is not relevant. Under section 306(c)(3) of the FD&C act, FDA considers the nature and seriousness of the offense. Ms. Ngo admitted to knowingly and repeatedly falsifying clinical trial records. Additionally, the inclusion of a provision in Ms. Ngo's plea agreement that prevents her from engaging in clinical research ''during any term of probation or supervised release'' evinces concern by the prosecution that she would continue to violate the law if involved in clinical research.

As set forth in the proposal to debar, ''[t]he creation and submission of falsified clinical trial data undermines FDA's determination of safety, effectiveness, and quality of the drugs the studies were designed to assess.'' Although the scope of conduct to which Ms. Ngo admitted during the criminal proceedings may have been limited to a few patients, submitting any false or fabricated data to the FDA is a serious offense that compromises the public health. Further, it is irrelevant that Eli Lilly ultimately did not use any of her information ''in a detrimental way.'' Had Ms. Ngo's conduct gone undetected and Eli Lilly submitted a new drug application containing the falsified data, FDA might have relied on her fabricated information to approve a new drug product, which reliance could have compromised the public health. Additionally, Ms. Ngo's lack of financial gain from her conduct does not diminish the nature and seriousness of her offense. Accordingly, Ms. Ngo has failed to create a genuine and material factual dispute with respect to the nature and seriousness of her offense.

Ms. Ngo next argues that, because she has not been involved in clinical trials since entering her guilty plea, there are ''reasonable assurances'' that ''the offense will not happen again.'' Ms. Ngo appears to be referencing the consideration under section 306(c)(3)(D) of the FD&C Act, where FDA must consider, *where applicable,* ''whether the extent to which changes in ownership, management, or operations have corrected the causes of any offense involved and provide reasonable assurances that the offense will not occur in the future.'' The considerations in section 306(c)(3) of the FD&C Act are not only for individuals but also for corporations, partnerships, and associations subject to permissive debarment. The consideration at issue does not typically apply to individuals because individuals are incapable of changes in ownership or management and could only alter the current operations of a business enterprise in which they are currently engaged. Even assuming for the sake of argument that an individual could point to changes in his or her current business practices as an applicable consideration under section 306(c)(3) of the FD&C Act, Ms. Ngo offers no actual facts to support her assertion that there are reasonable assurances that the offense will not occur again in the future; therefore, her unsubstantiated contention that, because she has not been involved in clinical trials since entering her guilty plea provides reasonable assurances that she will not commit the offense again, fails to create a genuine and substantial issue of fact that warrants a hearing.

Finally, Ms. Ngo argues that the maximum period of debarment is inappropriate for first-time offenders. While the Agency does consider prior convictions involving matters within the FDA's jurisdiction under section 306(c)(3)(F) of the FD&C Act, that consideration is only one of several that FDA considers in determining the appropriateness and period of debarment under section 306(c)(3). Ms. Ngo knowingly and repeatedly falsified clinical data records. FDA has determined that the conduct underlying her offense, combined with her failure to take any voluntary steps to mitigate the effect of her offense on the public, is sufficiently serious to warrant a 5-year period of debarment, even though she does not have any prior convictions involving matters within the Agency's jurisdiction.

III. Findings and Order

Therefore, the Chief Scientist, under section 306(b)(2)(B)(i)(I) of the FD&C Act and under the authority delegated to her by the Commissioner of Food and Drugs, finds: (1) That Ms. Ngo has been convicted of a misdemeanor under Federal law for conduct relating to the development or approval of a drug product or otherwise relating to the regulation of a drug product under the FD&C Act and (2) that the conduct underlying the conviction undermines the process for the regulation of drugs. FDA has considered the relevant factors listed in section 306(c)(3) of the FD&C Act and determined that a debarment of 5 years is appropriate.

As a result of the foregoing findings, Ms. Ngo is debarred for 5 years from providing services in any capacity to a person with an approved or pending drug product application under section 505, 512, or 802 of the FD&C Act (21 U.S.C. 335, 360b, or 382), or under section 351 of the Public Health Service Act (42 U.S.C. 262), effective August 2, 2021 (*see* 21 U.S.C. 335a(c)(1)(B) and (c)(2)(A)(iii) and 21 U.S.C. 321(dd)). Any person with an approved or pending drug product application, who knowingly uses the services of Ms. Ngo, in any capacity during her period of debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Ngo, during her period of debarment, provides services in any capacity to a person with an approved or pending drug product application, that person will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug applications submitted by or with the assistance of Ms. Ngo during her period of debarment (section 306(c)(1)(B) of the FD&C Act).

Dated: July 27, 2021.

Denise Hinton,

Chief Scientist.

[FR Doc. 2021–16352 Filed 7–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2002–N–0314]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Request for Samples and Protocols

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 1, 2021.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.*

Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0206. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Request for Samples and Protocols

OMB Control Number 0910–0206—Extension

This information collection supports Agency regulations. Under section 351 of the Public Health Service Act (42 U.S.C. 262), FDA has the responsibility to issue regulations that prescribe standards designed to ensure the safety, purity, and potency of biological products and to ensure that the biologics licenses for such products are only issued when a product meets the prescribed standards. Under § 610.2 (21 CFR 610.2), the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research may at any time require manufacturers of licensed biological products to submit to FDA samples of any lot, along with the protocols showing the results of applicable tests, prior to distributing the lot of the product. In addition to § 610.2, there are other regulations that require the submission of samples and protocols for specific licensed biological products: §§ 660.6, 660.36, and 660.46 (21 CFR 660.6, 660.36, and 660.46).

Section 660.6(a) provides requirements for the frequency of submission of samples from each lot of Antibody to Hepatitis B Surface Antigen product, and § 660.6(b) provides the requirements for the submission of a protocol containing specific information along with each required sample. For § 660.6 products subject to official release by CBER, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history of manufacture of the product, including all results of each test for which test results are requested by CBER. After official release is no longer required, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Section 660.36(a) requires, after each routine establishment inspection by FDA, the submission of samples from a lot of final Reagent Red Blood Cell product along with a protocol containing specific information. Section 660.36(a)(2) requires that a protocol contain information, including, but not limited to, manufacturing records, certain test records, and identity test results. Section 660.36(b) requires a copy of the antigenic constitution matrix specifying the antigens present or absent to be submitted to the CBER Director at the time of initial distribution of each lot.

Section 660.46(a) contains requirements as to the frequency of submission of samples from each lot of Hepatitis B Surface Antigen product, and § 660.46(b) contains the requirements as to the submission of a protocol containing specific information along with each required sample. For § 660.46 products subject to official release by CBER, one sample from each filling of each lot is required to be submitted along with a protocol consisting of a summary of the history or manufacture of the product, including all results of each test for which test results are requested by CBER. After notification of official release is received, one sample along with a protocol is required to be submitted at 90-day intervals. In addition, samples, which must be accompanied by a protocol, may at any time be required to be submitted to CBER if continued evaluation is deemed necessary.

Samples and protocols are required by FDA to help ensure the safety, purity, or potency of the product because of the potential lot-to-lot variability of a product produced from living organisms. In cases of certain biological products (*e.g.,* Albumin, Plasma Protein Fraction, and therapeutic biological products) that are known to have lot-to-lot consistency, official lot release is not normally required. However, submissions of samples and protocols of these products may still be required for surveillance, licensing, and export purposes, or in the event that FDA obtains information that the manufacturing process may not result in consistent quality of the product.

The following burden estimate is for the protocols required to be submitted with each sample. The collection of samples is not a collection of information under 5 CFR 1320.3(h)(2). Respondents to the collection of information under § 610.2 are manufacturers of licensed biological products. Respondents to the collection of information under §§ 660.6(b), 660.36(a)(2) and (b), and 660.46(b) are manufacturers of the specific products referenced previously in this document. The estimated number of respondents for each regulation is based on the annual number of manufacturers that submitted samples and protocols for biological products, including submissions for lot release, surveillance, licensing, or export. Based on information obtained from FDA's database system, approximately 75 manufacturers submitted samples and protocols in fiscal year (FY) 2020 under the regulations cited previously in this document. FDA estimates that approximately 72 manufacturers submitted protocols under § 610.2, and 3 manufacturers submitted protocols under the regulation (§ 660.6) for the other specific product. FDA received no submissions under §§ 660.36 or 660.46; however, FDA is using the estimate of one protocol submission under each regulation in the event that protocols are submitted in the future.

The estimated total annual responses are based on FDA's final actions completed in FY 2020 for the various submission requirements of samples and protocols for the licensed biological products. The average burden per response is based on information provided by industry. The burden estimates provided by industry ranged from 1 hour to 5.5 hours. Under § 610.2, the hours per response are based on the average of these estimates and rounded to 3 hours. Under the remaining regulations, the average burden per response is based on the higher end of the estimate (rounded to 5 or 6 hours) because more information is generally required to be submitted in the other protocols than under § 610.2.

In the **Federal Register** of March 16, 2021 (86 FR 14448), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
610.2, Requests for Samples and Protocols; Official Release	72	82.972	5,974	3	17,922
660.6(b), Protocols	3	4	12	5	60
660.36(a)(2) and (b), Samples and Protocols	1	1	1	6	6
660.46(b), Protocols	1	1	1	5	5
Total	77		5,988		17,993

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall decrease of 1,463 hours and a corresponding decrease of 491 responses. We attribute this adjustment to a decrease in the number of submissions we received over the last few years.

Dated: July 27, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–16384 Filed 7–30–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies Federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

FOR FURTHER INFORMATION CONTACT: Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Donovan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: In accordance with Section 9.19 of the Mandatory Guidelines, a notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list.*

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Pubic Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens: At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130 (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

Cordant Health Solutions, 2617 East L Street, Tacoma, WA 98421, 800–442–0438 (Formerly: STERLING Reference Laboratories)

Desert Tox, LLC, 5425 E Bell Rd, Suite 125, Scottsdale, AZ 85254, 602–457–5411/623–748–5045

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare*, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387,

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)

Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

Legacy Laboratory Services Toxicology, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088, Testing for Veterans Affairs (VA) Employees Only

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840

Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Redwood Toxicology Laboratory, 3700 Westwind Blvd., Santa Rosa, CA 95403, 800–255–2159

US Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Anastasia Marie Donovan,

Policy Analyst, Division of Workplace Programs.

[FR Doc. 2021–16385 Filed 7–30–21; 8:45 am]

BILLING CODE 4160–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (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.

Proposed Project: Government Performance and Results Act (GPRA) Client/Participant Outcomes Measure—(OMB No. 0930–0208)—Revision

SAMHSA is requesting approval to modify its existing CSAT Client-level GPRA instrument by removing 40 questions and adding 41 questions to its existing CSAT Client-level GPRA instrument resulting in a net addition of 1 question. Currently, the information collected from this instrument is

entered and stored in SAMSHA's Performance Accountability and Reporting System, which is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 reporting requirements that quantify the effects and accomplishments of its discretionary grant programs, which are consistent with OMB guidance.

SAMHSA will use the data for annual reporting required by GPRA and comparing baseline with discharge and follow-up data. GPRA requires that SAMHSA's fiscal year report include actual results of performance monitoring for the three preceding fiscal years. The additional information collected through this process will allow SAMHSA to: (1) Report results of these performance outcomes; (2) maintain consistency with SAMHSA-specific performance domains, and (3) assess the accountability and performance of its discretionary grant programs including a focus on health equity.

In revising the CSAT–GPRA tool, CSAT sought to improve functionality while also eliciting programmatic information that demonstrates impact at the client level. In this way, data from the revised GPRA tool can be used to assess resource allocation and to delineate who we serve, how we serve them, and how the program impacts clients from entry to discharge. The tool reflects CSAT's desire to elicit pertinent client and program level data that can be used to not only guide future programs and practice, but to also respond to stakeholder, congressional and agency enquiries.

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

SAMHSA tool	Number of respondents	Responses per respondent	Total number of responses	Burden hours per response	Total burden hours	Hourly wage [1]	Total hour cost
Baseline Interview Includes SBIRT Brief TX, Referral to TX, and Program-specific questions	179,668	1	179,668	0.6	107,801	$24.78	$2,671,309
Follow-Up Interview with Program-specific questions [2]	143,734	1	143,734	0.6	86,240	24.78	2,137,027
Discharge Interview with Program-specific questions [3]	93,427	1	93,427	0.6	56,056	24.78	1,389,068
SBIRT Program—Screening Only	594,192	1	594,192	0.13	77,245	24.78	1,914,131
SBIRT Program—Brief Intervention Only Baseline	111,411	1	111,411	0.2	22,282	24.78	552,148
SBIRT Program—Brief Intervention Only Follow-Up [2]	89,129	1	89,129	0.2	17,826	24.78	441,728
SBIRT Program—Brief Intervention Only Discharge [3]	57,934	1	57,934	0.2	11,587	24.78	287,126
CSAT Total	1,269,495		1,269,495		379,037		9,392,537

[1] The hourly wage estimate is $21.23 based on the Occupational Employment and Wages, Mean Hourly Wage Rate for 21–1011 Substance Abuse and Behavioral Disorder Counselors = $24.78/hr. as of May 11, 2021. (*http://www.bls.gov/oes/current/oes211011.htm.* Accessed on May 11, 2021.)

[2] It is estimated that 80% of baseline clients will complete this interview.

[3] It is estimated that 52% of baseline clients will complete this interview.

Note: Numbers may not add to the totals due to rounding and some individual participants completing more than one form.

Send comments to Carlos D. Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *Carlos.Graham@samhsa.hhs.gov.* Written comments should be received by October 1, 2021.

Carlos Graham,

Social Science Analyst.

[FR Doc. 2021–16405 Filed 7–30–21; 8:45 am]

BILLING CODE 4162–20–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) 276–0361.

Project: Revision of Mental Health Client/Participant Outcome Measures and Infrastructure, Prevention, and Mental Health Promotion Indicators (OMB No. 0930–0285)

SAMHSA is requesting approval for revisions to the previously approved instruments and data collection activities for the Government Performance and Results Act (GPRA) Center Mental Health Services (CMHS) (OMB No. 0930–0285) that expires on February 28, 2022.

To be fully accountable for the spending of federal funds, SAMHSA requires all programs to collect and report data to ensure that program goals and objectives are met. Data is collected and used to monitor and improve performance of each program and ensure appropriate and thoughtful spending of federal funds.

SAMHSA requests the following revisions to the National Outcome Measures (NOMS) Mental Health Client/Participant Outcome measures: (1) Merge the CMHS NOMS Child Client-level Measures for Discretionary Programs data collection instrument with the current CMHS NOMS Adult Client-level Measures for Discretionary Programs data collection instrument; (2) delete questions for data not being utilized for program monitoring and quality improvement; (3) reduce grantee burden by shifting questions for a five-point psychometric response scale to ''Yes'', ''No'', ''No response'', or ''Not applicable'' responses; (4) modify IDC–10 diagnoses to expand the F40–48, F60–63, and F90–99 codes to allow for more specificity. Also, add ICD–10 ''Z'' codes to allow for a focus on social determinants of health that may affect the diagnosis, course, prognosis, or treatment of a client/consumer mental disorder; (6) shift reporting NOMS data to baseline assessment, 3-month or 6-month reassessment, and a final clinical discharge assessment; (7) reduce the number of physical health indictors and reporting frequency from quarterly to three points in time (baseline, 3- or 6-month reassessment, clinical discharge) to further reduce grantee burden.

SAMHSA also requests the following revisions to the Infrastructure, Prevention, and Mental Health Promotion indicators: (1) Delete ten indicators not used by any SAMSHA programs (A3, A6, F1, F2, F3, O2, T4, WD1, WD3, and WD4); (2) revise two indicators to provide more clarity (A1 and A5); and (3) add ten indicators to reflect program developments during the past three years (R2, S2, S3, T5, T6, T7, T8, TR2, TR3, and TR4).

These changes will lessen grantee burden with data collection and improve capacity to report qualitative performance and quantitative outcomes for all discretionary grant programs, including: Demographic characteristics of clients served; clinical characteristics of clients served before, during, and after receipt of services; numbers of clients served; and characteristics of services and activities provided to clients.

Currently, the information collected from this instrument is entered and stored on SAMHSA's Performance Accountability and Reporting System (SPARS), which is a real-time, performance management system that captures information on mental health and substance abuse treatment services delivered in the United States. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act of 2010 (GPRMA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs, which are consistent with OMB guidance.

SAMHSA will use the data collected for annual reporting required by GPRMA, to describe and understand changes in outcomes from baseline to follow-up to discharge. SAMHSA and its Centers will use the data for annual reporting comparing baseline with discharge and follow-up data. SAMHSA's report for each fiscal year will include actual results of performance monitoring for the three preceding fiscal years. Information collected through this request will allow SAMHSA to report on the results of these performance outcomes as well as be consistent with SAMHSA-specific performance domains, and to assess the accountability and performance of its discretionary and formula grant programs. The additional information collected through this request will allow SAMHSA to improve its ability to assess the impact of its programs on key outcomes of interest and to gather vital diagnostic information about clients served by discretionary grant programs.

The requested changes will result in a reduction of total burden hours. Currently, there are 104,168 total burden hours in the OMB-approved inventory. SAMHSA is requesting a reduction to 68,673 hours or an estimated decrease of 35,494 burden hours. The proposed estimate of time to collect data and complete the instruments is shown in Table 1.

TABLE 1—ESTIMATES OF ANNUALIZED HOUR BURDEN

SAMHSA tool	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Client-level baseline interview	40,280	1	40,280	0.33	30,901
Client-level 3- or 6-month reassessment interview	40,280	1	40,280	0.33	30,901
Client-level clinical discharge interview	6,668	1	6,668	0.33	2,200
Section H Physical Health Data Baseline	39,231	1	39,231	.10	3,923
Section H Program Specific Data: Baseline, 3- or 6-month reassessment, and clinical discharge	14,800	2	29,600	.08	2,368
Subtotal	141,259		154,059		68,673
Infrastructure development, prevention, and mental health promotion quarterly record abstraction	942	4	3,768	2.0	7,536
Total	142,201		157,827		104,168

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fisher Lane, Room 15E57A, Rockville, MD 20852 *OR* email him a copy at *carlos.graham@samhsa.hhs.gov.* Written comments should be received by October 1, 2021.

Carlos Graham,

Social Science Analyst.

[FR Doc. 2021–16406 Filed 7–30–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (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.

Proposed Project: Opioid Drugs in Maintenance and Detoxification Treatment of Opioid Dependence—42 CFR Part 8 (OMB No. 0930–0206) and Opioid Treatment Programs (OTPs)—Extension

42 CFR part 8 establishes a certification program managed by SAMHSA's Center for Substance Abuse Treatment (CSAT). The regulation requires that Opioid Treatment Programs (OTPs) be certified. ''Certification'' is the process by which SAMHSA determines that an OTP is qualified to provide opioid treatment under the Federal opioid treatment standards established by the Secretary of Health and Human Services. To become certified, an OTP must be accredited by a SAMHSA-approved accreditation body. The regulation also provides standards for such services as individualized treatment planning, increased medical supervision, and assessment of patient outcomes. This submission seeks continued approval of the information collection requirements in the regulation and of the forms used in implementing the regulation.

SAMHSA currently has approval for the Application for Certification to Use Opioid Drugs in a Treatment Program Under 42 CFR 8.11 (Form SMA–162); the Application for Approval as Accreditation Body Under 42 CFR 8.3(b) (Form SMA–163); and the Exception Request and Record of Justification Under 42 CFR 8.12 (Form SMA–168), which may be used on a voluntary basis by physicians when there is a patient care situation in which the physician must make a treatment decision that differs from the treatment regimen required by the regulation. Form SMA–168 is a simplified, standardized form to facilitate the documentation, request, and approval process for exceptions.

SAMHSA believes that the recordkeeping requirements in the regulation are customary and usual practices within the medical and rehabilitative communities and has not calculated a response burden for them. The recordkeeping requirements set forth in 42 CFR 8.4, 8.11 and 8.12 include maintenance of the following: 5-year retention by accreditation bodies of certain records pertaining to accreditation; documentation by an OTP of the following: A patient's medical examination when admitted to treatment, A patient's history, a treatment plan, any prenatal support provided the patient, justification of unusually large initial doses, changes in a patient's dosage schedule, justification of unusually large daily doses, the rationale for decreasing a patient's clinic attendance, and documentation of physiologic dependence.

The tables that follows summarizes the annual reporting burden associated with the regulation, including burden associated with the forms. There are no changes being made to the forms.

Form	Number of respondents	Responses/ respondent	Total responses	Hours/ response	Total hours
Estimated Annual Reporting Requirement Burden for Accreditation Bodies					
SMA–163	54	26.055	1,407	0.28	394
Estimated Annual Reporting Requirement Burden for Opioid Treatment Programs					
SMA–162	651.33	17.976	11,708.91		
SMA–168	1,302.67	17.977	23,418.09		
Subtotal	1,954	17.977	35,127	0.08	2,902
Total			36,534		3,296

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, Room 15–E57A, 5600 Fishers Lane, Rockville, MD 20850 *OR* email him a copy at *carlos.graham@samhsa.hhs.gov.* Written comments should be received within 60 days of this notice.

Carlos Graham,

Statistician.

[FR Doc. 2021–16402 Filed 7–30–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed project or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer at (240) 276–0361.

Comments are invited on: (a) Whether the proposed collections of information are 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (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.

Project: State Opioid Response (SOR)/ Tribal Opioid Response (TOR) Program Instrument (OMB No. 0930–0384)—Revision

SAMHSA is requesting approval to modify its existing CSAT SOR/TOR Program Instrument by (1) collapsing the original three questions into two questions for clarity and (2) adding ten questions, in order to collect information on Congressionally mandated and programmatic activities and comply with reporting requirements. The program-level information is collected quarterly and entered and stored in SAMHSA's Performance Accountability and Reporting System, which is a real-time, performance management system that captures information on the substance abuse prevention and treatment and mental health services delivered in the United States. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Modernization Act (GPRA) of 2010 reporting requirements that quantify the effects and accomplishments of its discretionary grant programs.

The SOR/TOR programs were first authorized under Title II Division H of the Consolidated Appropriations Act, 2018, Public Law 115–141. SOR/TOR programs aim to address the opioid crisis by increasing access to medication-assisted treatment using the three FDA-approved medications for the treatment of Opioid Use Disorder (OUD), reducing unmet treatment need, and reducing opioid overdose-related deaths through the provision of prevention, treatment and recovery activities for OUD (including illicit use of prescription opioids, heroin, and fentanyl and fentanyl analogs).

SAMHSA is proposing to revise the SOR/TOR Program Instrument data collection instrument (OMB No. 0930–0384), in order to collect information on Congressionally mandated and programmatic activities and comply with reporting requirements.

SAMHSA developed the SOR/TOR Program Instrument to collect minimum data on naloxone purchase and distribution, but the SOR/TOR programs are unique in that they have prevention requirements. SOR/TOR grantees are required to engage in the following prevention activities: (1) Implement prevention and education services, including training of peers and first responders on recognition of opioid overdose and appropriate use of the opioid overdose antidote naloxone, (2) develop evidence-based community prevention efforts, including strategic messaging on the consequences of opioid misuse, and (3) purchase and distribute naloxone and train on its use. The revised tool will allow SAMHSA to collect data on the required education and prevention activities, and better assess grantee performance on these activities.

Based on a recent United States Government Accountability Office (GAO) Report to Congress GAO 21–96, ''Drug Misuse: Agencies Have Not Fully Identified How Grants That Can Support Drug Prevention Education Programs Contribute to National Goals,'' [1] GAO found that SAMHSA's performance measures for the SOR program partially reflect its core program activities, and that although SAMHSA reported three performance measures for the SOR program, all three measures focused on treatment or recovery services only. GAO recommended, and SAMHSA committed to, implementing the following: ''The Secretary of Health and Human Services should determine how the State Opioid Response program contributes to the prevention goals of the National Drug Control Strategy and develop performance measures that relate to achieving those goals including the prevention education goal.'' Collection of the data in the revised tool will enable SAMHSA to implement the recommendations of GAO.

Finally, the revisions will assist SAMHSA in providing comprehensive data on the full range of required activities to inform Congressionally mandated reports for the SOR program.

In order to address these issues, SAMHSA is proposing to (1) collapse the three questions into two questions for clarity and (2) add ten questions, in order to collect information on Congressionally mandated and programmatic activities and comply with reporting requirements. A summary of the proposed changes includes:

- The revised question will provide CSAT with clarification on the purchase and distribution of naloxone kits.
- The ten additional questions will provide data on the following:
  - Reported overdose reversals;
  - Purchase and distribution of fentanyl test strips;
  - Training of first responders and key community sectors on recognizing an opioid overdose and the appropriate use of naloxone overdose reversal kits;
  - Educating individuals, including school-aged children, on the consequences of opioid and/or stimulant misuse using strategic messaging and prevention activities;
  - Training individuals to provide school-based prevention and education activities to school-aged children; and
  - Providing targeted prevention outreach activities to underserved and/or diverse populations.

[1] United States Government Accountability Office. (2020, November). Drug Misuse: Agencies Have Not Fully Identified How Grants That Can Support Drug Prevention Education Programs Contribute to National Goals. *https://www.gao.gov/assets/gao-21-96.pdf.*

TABLE 1—ESTIMATE OF ANNUALIZED HOUR BURDEN FOR SOR/TOR GRANTEES

SAMHSA data collection	Number of respondents	Responses per respondent	Total number of responses	Burden hours per response	Total burden hours	Hourly wage [2]	Total wage cost
Grantee-Level Instrument	159	4	636	.30	190.80	$24.78	$4,728.02
CSAT Total	159	4	636	.30	190.80	24.78	4,728.02

Send comments to Carlos Graham, SAMHSA Reports Clearance Officer, 5600 Fishers Lane, Room 15E57–A, Rockville, Maryland 20857, *OR* email a copy to *Carlos.Graham@samhsa.hhs.gov.* Written comments should be received by October 1, 2021.

Carlos Graham,

Social Science Analyst.

[FR Doc. 2021–16407 Filed 7–30–21; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: New or modified Base (1-percent annual chance) Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, and/or regulatory floodways (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: Each LOMR was finalized as 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 *https://msc.fema.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://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 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and 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 information is 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).

This new or modified flood hazard information, 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.

This new or modified flood hazard determinations are used to meet the floodplain management requirements of the NFIP and 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 *https://msc.fema.gov.*

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Florida:					
Alachua (FEMA Docket No.: B–2125).	Unincorporated areas of Alachua County (20–04–2956P).	Ms. Michele L. Lieberman, Alachua County Manager, 12 Southeast 1st Street, Gainesville, FL 32601.	Alachua County Public Works Department, 5620 Northwest 120th Lane, Gainesville, FL 32653.	July 6, 2021	120001

[2] The hourly wage estimate is $24.78 based on the Occupational Employment and Wages, Mean Hourly Wage Rate for 21–1018 Substance Abuse, Behavioral Disorder, and Mental Health Counselors = $24.78/hr. as of May 2020 (*https://www.bls.gov/oes/current/oes211018.htm* Accessed on May 4, 2021.)

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Gadsden (FEMA Docket No.: B–2119).	Unincorporated areas of Gadsden County, (20–04–5221P).	The Honorable Anthony O. Viegbesie, Commissioner, Gadsden County, 9–B East Jefferson Street, Quincy, FL 32353.	Gadsden County Public Works Department, 1284 High Bridge Road, Quincy, FL 32351.	July 2, 2021	120091
Monroe (FEMA Docket No.: B–2125).	Unincorporated areas of Monroe County (21–04–1027P).	The Honorable Michelle Coldiron, Mayor, Monroe County Board of Commissioners, 25 Ships Way, Big Pine Key, FL 33043.	Monroe County Building Department, 2798 Overseas Highway, Suite 300, Marathon, FL 33050.	July 12, 2021	125129
Volusia (FEMA Docket No.: B–2133).	City of Daytona Beach (20–04–3525P).	Mr. James Chisholm, Manager, City of Daytona Beach, 301 South Ridgewood Avenue, Daytona Beach, FL 32114.	Utilities Engineering Division, 125 Basin Street, Suite 100, Daytona Beach, FL 32114.	July 2, 2021	125099
Volusia (FEMA Docket No.: B–2133).	Unincorporated areas of Volusia County (20–04–3525P).	Mr. George Recktenwald, Volusia County Manager, 123 West Indiana Avenue, Deland, FL 32720.	Volusia County Planning and Development Services Department, 123 West Indiana Avenue, Deland, FL 32720.	July 2, 2021	125155
Georgia:					
Barrow (FEMA Docket No.: B–2125).	Unincorporated areas of Barrow County (20–04–3669P).	The Honorable Pat Graham, Chair, Barrow County Board of Commissioners, 30 North Broad Street, Winder, GA 30680.	Barrow County Planning and Community Development, 30 North Broad Street, Winder, GA 30680.	July 8, 2021	130497
Henry (FEMA Docket No.: B–2119).	Unincorporated areas of Henry County (20–04–2920P).	Ms. Cheri Hobson Matthews, Henry County Manager, 140 Henry Parkway, McDonough, GA 30253.	Henry County Stormwater Department, 347 Phillips Drive, McDonough, GA 30253.	July 1, 2021	130468
Pickens (FEMA Docket No.: B–2119).	City of Jasper (20–04–1908P).	The Honorable Steve Lawrence, Mayor, City of Jasper, 200 Burnt Mountain Road, Jasper, GA 30143.	City Hall, 200 Burnt Mountain Road, Jasper, GA 30143.	July 2, 2021	130375
Massachusetts: Barnstable (FEMA Docket, No.: B–2133).	Town of Barnstable (20–01–1587P).	Mr. Mark S. Ells, Manager, Town of Barnstable, 367 Main Street, Hyannis, MA 02601.	Inspectional Services Department, 200 Main Street, Hyannis, MA 02601.	July 6, 2021	250001
Montana:					
Gallatin (FEMA Docket, No.: B–2130).	City of Bozeman (20–08–0500P).	Mr. Jeff Mihelich, City of Bozeman Manager, 121 North Rouse Avenue, Bozeman, MT 59715.	City Hall, 20 East Olive Street, Bozeman, MT 59715.	July 12, 2021	300028
Gallatin (FEMA Docket, No.: B–2130).	Unincorporated areas of Gallatin County (20–08–0500P).	The Honorable Scott MacFarlane, Chairman, Gallatin County Commission, 311 West Main Street, Room 306, Bozeman, MT 59715.	Gallatin County Department of Planning and Community Development, 311 West Main Street, Room 108, Bozeman, MT 59715.	July 12, 2021	300027
North Carolina:					
Forsyth (FEMA Docket, No.: B–2130).	City of Winston-Salem (21–04–1235X).	The Honorable Allen Joines, Mayor, City of Winston-Salem, P.O. Box 2511, Winston-Salem, NC 27102.	Inspection Department, 100 East 1st Street, Suite 328, Winston-Salem, NC 27101.	July 8, 2021	375360
Forsyth (FEMA Docket, No.: B–2130).	Unincorporated areas of Forsyth County (21–04–1235X).	The Honorable David R. Plyler, Chairman, Forsyth County Board of Commissioners, 201 North Chestnut Street, Winston-Salem, NC 27101.	Forsyth County Planning Board Office, 100 East 1st Street, Winston-Salem, NC 27101.	July 8, 2021	375349
Orange (FEMA Docket No.: B–2136).	City of Mebane (21–04–0010P).	The Honorable Ed Hooks, Mayor, City of Mebane, 106 East Washington Street, Mebane, NC 27302.	Mebane Planning Department, 102 South 5th Street, Mebane, NC 27302	July 15, 2021	370390
Texas:					
Archer (FEMA Docket No.: B–2125).	City of Scotland (21–06–0024P).	The Honorable Ron Hoff, Mayor, City of Scotland, P.O. Box 32, Scotland, TX 76379.	City Hall, 727 Avenue L, Scotland, TX 76379.	July 9, 2021	481280
Archer (FEMA Docket No.: B–2125).	Unincorporated areas of Archer County (21–06–0024P).	The Honorable Randall C. Jackson, Archer County Judge, P.O. Box 458, Archer City, TX 76351.	Archer County Courthouse, Emergency Management Office, 100 South Center Street, Archer City, TX 76351.	July 9, 2021	481078
Bexar (FEMA Docket No.: B–2130).	City of Live Oak (20–06–1270P).	The Honorable Mary M. Dennis, Mayor, City of Live Oak, 8001 Shin Oak Drive, Live Oak, TX 78233.	City Hall, 8001 Shin Oak Drive, Live Oak, TX 78233.	July 6, 2021	480043
Bexar (FEMA Docket No.: B–2130).	City of San Antonio (20–06–1270P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvement, Storm Water Division, 114 West Commerce Street, San Antonio, TX 78205.	July 6, 2021	480045
Bexar (FEMA Docket No.: B–2130).	City of San Antonio (21–06–0487P).	The Honorable Ron Nirenberg, Mayor, City of San Antonio, P.O Box 839966, San Antonio, TX 78283.	Transportation and Capital Improvement, Storm Water Division, 114 West Commerce Street, San Antonio, TX 78205.	July 6, 2021	480045

State and county	Location and case No.	Chief executive officer of community	Community map repository	Date of modification	Community No.
Bexar (FEMA Docket No.: B–2130).	City of Selma (20–06–1270P).	The Honorable Tom Daly, Mayor, City of Selma, 9375 Corporate Drive, Selma, TX 78154.	City Hall, 9375 Corporate Drive, Selma, TX 78154.	July 6, 2021	480046
Denton (FEMA Docket No.: B–2125).	City of Corinth (21–06–1194P).	The Honorable Bill Heidemann, Mayor, City of Corinth, 3300 Corinth Parkway, Corinth, TX 76208.	Engineering Department, 3300 Corinth Parkway, Corinth, TX 76208.	July 12, 2021	481143
Harris (FEMA Docket No.: B–2125).	Unincorporated areas of Harris County (19–06–3141P).	The Honorable Lina Hidalgo, Harris County Judge, 1001 Preston Street, Suite 911, Houston, TX 77002.	Harris County Permit Office, 10555 Northwest Freeway, Suite 120, Houston, TX 77002.	July 12, 2021	480287
Kaufman (FEMA Docket No.: B–2125).	Unincorporated areas of Kaufman County (20–06–3077P).	The Honorable Hal Richards, Kaufman County Judge, 100 West Mulberry Street, Kaufman, TX 75142.	Kaufman County Courthouse, 106 West Grove Street, Kaufman, TX 75142.	July 9, 2021	480411
Rockwall (FEMA Docket No.: B–2133).	City of Royse City (20–06–3214P).	The Honorable Clay Ellis, Mayor Pro Tem, City of Royse City, P.O. Box 638, Royse City, TX 75189.	City Hall, 305 North Archer Road, Royse City, TX 75189.	July 9, 2021	480548
Travis (FEMA Docket No.: B–2125).	City of Rollingwood (20–06–2815P).	The Honorable Mike Dyson, Mayor, City of Rollingwood, 403 Nixon Drive, Rollingwood, TX 78746.	City Hall, 403 Nixon Drive, Rollingwood, TX 78746.	July 12, 2021	481029
Williamson (FEMA Docket No.: B–2125).	City of Round Rock (20–06–3569P).	The Honorable Craig Morgan, Mayor, City of Round Rock, 221 East Main Street, Round Rock, TX 78664.	Department of Utilities and Environmental Services, 3400 Sunrise Road, Round Rock, TX 78665.	July 1, 2021	481048
West Virginia:					
Cabell (FEMA Docket No.: B–2133).	City of Huntington (21–03–0357P).	The Honorable Steve Williams, Mayor, City of Huntington, P.O. Box 1659, Huntington, WV 25701.	Planning and Zoning Department, 800 5th Avenue, Suite 2, Huntington, WV 25701.	July 7, 2021	540018
Cabell (FEMA Docket No.: B–2133).	Unincorporated areas of Cabell County (21–03–0357P).	Ms. Beth Thompson, Cabell County Administrator, 750 5th Avenue, Suite 300, Huntington, WV 25701.	Cabell County Assessor's Office, 750 5th Avenue, Suite 300, Huntington, WV 25701.	July 7, 2021	540016

[FR Doc. 2021–16436 Filed 7–30–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2154]

Proposed Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Comments are requested on proposed flood hazard determinations, which may include additions or modifications of any Base Flood Elevation (BFE), base flood depth, Special Flood Hazard Area (SFHA) boundary or zone designation, or regulatory floodway on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports for the communities listed in the table below. The purpose of this notice is to seek general information and comment regarding the preliminary FIRM, and where applicable, the FIS report that the Federal Emergency Management Agency (FEMA) has provided to the affected communities. 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). In addition, the FIRM and FIS report, once effective, will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings.

DATES: Comments are to be submitted on or before November 1, 2021.

ADDRESSES: The Preliminary FIRM, and where applicable, the FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

You may submit comments, identified by Docket No. FEMA–B–2154, to Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov.*

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: FEMA proposes to make flood hazard determinations for each community listed below, in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR 67.4(a).

These proposed 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 flood hazard determinations are used to meet the floodplain management requirements of the NFIP and are used to calculate the appropriate flood insurance premium rates for new buildings built after the FIRM and FIS report become effective.

The communities affected by the flood hazard determinations are provided in the tables below. Any request for reconsideration of the revised flood hazard information shown on the Preliminary FIRM and FIS report that satisfies the data requirements outlined in 44 CFR 67.6(b) is considered an appeal. Comments unrelated to the flood hazard determinations also will be considered before the FIRM and FIS report become effective.

Use of a Scientific Resolution Panel (SRP) is available to communities in support of the appeal resolution process. SRPs are independent panels of experts in hydrology, hydraulics, and other pertinent sciences established to review conflicting scientific and technical data and provide recommendations for resolution. Use of the SRP only may be exercised after FEMA and local communities have been engaged in a collaborative consultation process for at least 60 days without a mutually acceptable resolution of an appeal. Additional information regarding the SRP process can be found online at *https://www.floodsrp.org/pdfs/srp_overview.pdf.*

The watersheds and/or communities affected are listed in the tables below. The Preliminary FIRM, and where applicable, FIS report for each community are available for inspection at both the online location *https://hazards.fema.gov/femaportal/prelimdownload* and the respective Community Map Repository address listed in the tables. For communities with multiple ongoing Preliminary studies, the studies can be identified by the unique project number and Preliminary FIRM date listed in the tables. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Barrow County, Georgia and Incorporated Areas **Project: 18–04–0003S Preliminary Date: September 22, 2020**	
City of Auburn	City Hall, 1369 4th Avenue, Auburn, GA 30011.
City of Statham	Planning and Zoning Department, 327 Jefferson Street, Statham, GA 30666.
City of Winder	City Hall, 25 East Midland Avenue, Winder, GA 30680.
Town of Bethlehem	City Hall, 750 Manger Avenue, Bethlehem, GA 30620.
Town of Braselton	Town Hall, 4982 Highway 53, Braselton, GA 30517.
Town of Carl	City Hall, 1690 Carl-Bethlehem Road, Auburn, GA 30011.
Unincorporated Areas of Barrow County	Barrow County Historic Courthouse, 30 North Broad Street, Winder, GA 30680.
Gwinnett County, Georgia and Incorporated Areas **Project: 18–04–0003S Preliminary Date: September 22, 2020**	
City of Dacula	City Hall, 442 Harbins Road, Dacula, GA 30019.
Town of Braselton	Town Hall, 4982 Highway 53, Braselton, GA 30517.
Unincorporated Areas of Gwinnett County	Gwinnett County Justice and Administration Center, 75 Langley Drive, Lawrenceville, GA 30046.
Hall County, Georgia and Incorporated Areas **Project: 18–04–0003S Preliminary Date: September 22, 2020**	
City of Flowery Branch	City Hall, 5410 West Pine Street, Flowery Branch, GA 30542.
City of Gainesville	Department of Water Resources, Administration Building, 757 Queen City Parkway, Gainesville, GA 30501.
City of Gillsville	City Hall, 6288 Highway 52, Gillsville, GA 30543.
City of Lula	City Hall, 6055 Main Street, Lula, GA 30554.
Town of Braselton	Town Hall, 4982 Highway 53, Braselton, GA 30517.
Unincorporated Areas of Hall County	Hall County Government Center, Engineering Division, 2875 Browns Bridge Road, Gainesville, GA 30504.

[FR Doc. 2021–16438 Filed 7–30–21; 8:45 am]

BILLING CODE 9111–23–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002; Internal Agency Docket No. FEMA–B–2153]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

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 Federal Regulations. 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 be finalized 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 90 days in which to request through the community that the Deputy Associate Administrator for Insurance and 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 *https://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: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://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 *https://msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Colorado:						
Adams	Unincorporated areas of Adams County (20–08–0723P).	The Honorable Eva J. Henry, Chair, Adams County Board of Commissioners, 4430 South Adams County Parkway, Suite C5000A, Brighton, CO 80601.	Adams County Community and Economic Development, 4430 Adams County Parkway, 1st Floor, Suite W2000, Brighton, CO 80601.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 28, 2021	080001
Boulder	City of Longmont (20–08–0847P).	The Honorable Brian Bagley, Mayor, City of Longmont, 350 Kimbark Street, Longmont, CO 80501.	Development Services Center, 385 Kimbark Street, Longmont, CO 80501.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 25, 2021	080027

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
El Paso	City of Colorado Springs (20–08–0822P).	The Honorable John Suthers, Mayor, City of Colorado Springs, 30 South Nevada Avenue, Suite 601, Colorado Springs, CO 80903.	Pikes Peak Regional Development Center, 2880 International Circle, Colorado Springs, CO 80910.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 27, 2021	080060
Weld	Town of Windsor (21–08–0116P).	The Honorable Paul Rennemeyer, Mayor, Town of Windsor, 301 Walnut Street, Windsor, CO 80550.	Town Hall, 301 Walnut Street, Windsor, CO 80550.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 1, 2021	080264
Weld	Unincorporated areas of Weld County (21–08–0116P).	The Honorable Steve Moreno, Chairman, Weld County Board of Commissioners, P.O. Box 758, Greeley, CO 80631.	Weld County Administration Building, 1150 O Street, Greeley, CO 80631.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 1, 2021	080266
Florida:						
Alachua	Unincorporated areas of Alachua County (21–04–0749P).	Ms. Michelle L. Lieberman, Alachua County Manager, 12 Southeast 1st Street, Gainesville, FL 32601.	Alachua County Public Works Department, 5620 Northwest 120th Lane, Gainesville, FL 32653.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 20, 2021	120001
Lee	Unincorporated areas of Lee County (21–04–1477P).	Mr. Roger Desjarlais, Lee County Manager, 2115 2nd Street, Fort Myers, FL 33901.	Lee County Building Department, 1500 Monroe Street, Fort Myers, FL 33901.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 20, 2021	125124
Lee	Village of Estero (21–04–1477P).	Mr. Steven R. Sarkozy, Village of Estero Manager, 9401 Corkscrew Palms Circle, Estero, FL 33928.	Village Hall, 9401 Corkscrew Palms Circle, Estero, FL 33928.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 20, 2021	120260
Monroe	Village of Islamorada (21–04–2470P).	The Honorable Buddy Pinder, Mayor, Village of Islamorada, 86800 Overseas Highway, Islamorada, FL 33036.	Building Department, 86800 Overseas Highway, Islamorada, FL 33036.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 18, 2021	120424
Palm Beach	Unincorporated areas of Palm Beach County (20–04–0988P).	Ms. Verdenia C. Baker, Palm Beach County Administrator, 301 North Olive Avenue, Suite 1101, West Palm Beach, FL 33401.	Palm Beach County Planning, Zoning and Building Department, 2300 North Jog Road, Room 1E–17, West Palm Beach, FL 33411.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 18, 2021	120192
Sarasota	Unincorporated areas of Sarasota County (21–04–1410P).	The Honorable Alan Maio, Chairman, Sarasota County Board of Commissioners, 1660 Ringling Boulevard, Sarasota, FL 34236.	Sarasota County Planning and Development Services Department, 1001 Sarasota Center Boulevard, Sarasota, FL 34240.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 13, 2021	125144
Sumter	City of Wildwood (20–04–3503P).	The Honorable Ed Wolf, Mayor, City of Wildwood, 100 North Main Street, Wildwood, FL 34785.	Public Works Department, 743 Huey Street, Wildwood, FL 34785.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 15, 2021	120299
Sumter	City of Wildwood (20–04–3653P).	The Honorable Ed Wolf, Mayor, City of Wildwood, 100 North Main Street, Wildwood, FL 34785.	Public Works Department, 743 Huey Street, Wildwood, FL 34785.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 15, 2021	120299
Sumter	Unincorporated areas of Sumter County (20–04–3503P).	The Honorable Garry Breeden, Chairman, Sumter County Board of Commissioners, 7375 Powell Road, Wildwood, FL 34785.	Sumter County Planning Department, 7375 Powell Road, Suite 115, Wildwood, FL 34785.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 15, 2021	120296
Sumter	Unincorporated areas of Sumter County (20–04–3653P).	The Honorable Garry Breeden, Chairman, Sumter County Board of Commissioners, 7375 Powell Road, Wildwood, FL 34785.	Sumter County Planning Department, 7375 Powell Road, Suite 115, Wildwood, FL 34785.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 15, 2021	120296
Kentucky: Hardin	City of Vine Grove (21–04–0296P).	The Honorable Pam Ogden, Mayor, City of Vine Grove, 300 West Main Street, Vine Grove, KY 40175.	City Hall, 300 West Main Street, Vine Grove, KY 40175.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 25, 2021	210096
Montana:						
Gallatin	City of Bozeman (20–08–0733P).	Mr. Jeff Mihelich, City of Bozeman Manager, 121 North Rouse Avenue, Bozeman, MT 59715.	City Hall, 20 East Olive Street, Bozeman, MT 59715.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 6, 2021	300028

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Date of modification	Community No.
Gallatin	Unincorporated areas of Gallatin County (20–08–0733P).	The Honorable Scott MacFarlane, Chairman, Gallatin County Commission, 311 West Main Street, Room 306, Bozeman, MT 59715.	Gallatin County Department of Planning and Community Development, 311 West Main Street, Room 108, Bozeman, MT 59715.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 6, 2021	300027
South Carolina:						
Horry.	City of North Myrtle Beach (21–04–0914P).	Mr. Michael Mahaney, Manager, City of North Myrtle Beach, 1018 2nd Avenue South, North Myrtle Beach, SC 29582.	Planning and Development Department, 1018 2nd Avenue South, North Myrtle Beach, SC 29582.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 27, 2021	450110
Texas:						
Collin	City of McKinney (21–06–0619P).	The Honorable George Fuller, Mayor, City of McKinney, P.O. Box 517, McKinney, TX 75070.	Engineering Department, 221 North Tennessee Street, McKinney, TX 75069.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 12, 2021	480135
Collin	Unincorporated areas of Collin County (21–06–0619P).	The Honorable Chris Hill, Collin County Judge, 2300 Bloomdale Road, Suite 4192, McKinney, TX 75071.	Collin County Engineering Department, 4690 Community Avenue, Suite 200, McKinney, TX 75071.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 12, 2021	480130
Dallas	City of Rowlett (21–06–0711P).	The Honorable TammyDana-Bashian Mayor, City of Rowlett, 4000 Main Street, Rowlett, TX 75088.	Community Development Department, 5702 Rowlett Road, Rowlett, TX 75089.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 15, 2021	480185
El Paso	City of El Paso (21–06–0100P).	The Honorable Oscar Leeser, Mayor, City of El Paso, 300 North Campbell Street, El Paso, TX 79901.	Flood Mitigation and Land Development Department, 801 Texas Avenue, El Paso, TX 79901.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 8, 2021	480214
El Paso	City of Socorro (21–06–0100P).	The Honorable Ivy Avalos, Mayor, City of Socorro, 124 South Horizon Boulevard, Socorro, TX 79927.	Planning and Zoning Department, 860 North Rio Vista Road, Socorro, TX 79927.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 8, 2021	481658
Montgomery	Unincorporated areas of Montgomery County (20–06–1594P).	The Honorable Mark J. Keough, Montgomery County Judge, 501 North Thompson Street, Suite 401, Conroe, TX 77301.	Montgomery County Commissioners Office, 501 North Thompson Street, Suite 103, Conroe, TX 77301.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 8, 2021	480483
Rockwall	City of Fate (21–06–0525P).	The Honorable David Billings, Mayor, City of Fate, 1900 C.D. Boren Parkway, Fate, TX 75087.	Planning and Development Department, 1900 C.D. Boren Parkway, Fate, TX 75087.	*https://msc.fema.gov/portal/advanceSearch.*	Nov. 1, 2021	480544
Williamson	City of Georgetown (21–06–0115P).	Mr. David Morgan, Manager, City of Georgetown, P.O. Box 409, Georgetown, TX 78626.	Mapping and GIS Department, 300–1 Industrial Avenue, Georgetown, TX 78626.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 14, 2021	480668
Williamson	Unincorporated areas of Williamson County (21–06–0115P).	The Honorable Bill Gravell, Jr., Williamson County Judge, 710 South Main Street, Suite 101, Georgetown, TX 78626.	Williamson County Engineering Department, 3151 Southeast Inner Loop, Georgetown, TX 78626.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 14, 2021	481079
Utah: Washington	City of Hurricane (20–08–1034P).	The Honorable John W. Bramall, Mayor, City of Hurricane, 147 North 870 West, Hurricane, UT 84737.	Engineering Department, 147 North 870 West, Hurricane, UT 84737.	*https://msc.fema.gov/portal/advanceSearch.*	Oct. 25, 2021	490172

[FR Doc. 2021–16437 Filed 7–30–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2021–0002]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the

communities listed in the table below. The FIRM and FIS report are the basis of the floodplain management measures that a 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 Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The date of November 19, 2021 has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *https://msc.fema.gov* by the date indicated above.

FOR FURTHER INFORMATION CONTACT: Rick Sacbibit, Chief, Engineering Services Branch, Federal Insurance and Mitigation Administration, FEMA, 400 C Street SW, Washington, DC 20472, (202) 646–7659, or (email) *patrick.sacbibit@fema.dhs.gov;* or visit the FEMA Mapping and Insurance eXchange (FMIX) online at *https://www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Insurance and Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *https://msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Michael M. Grimm,

Assistant Administrator for Risk Management, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Santa Rosa County, Florida and Incorporated Areas Docket No.: FEMA–B–2022	
City of Gulf Breeze	City Hall, 1070 Shoreline Drive, Gulf Breeze, FL 32561.
City of Milton	Planning and Development Department, 6738 Dixon Street, Milton, FL 32572.
Town of Jay	Town Hall, 3695 Highway 4, Jay, FL 32565.
Unincorporated Areas of Santa Rosa County	Santa Rosa County Public Services Department, 6051 Old Bagdad Highway, Milton, FL 32583.
Jones County, Iowa and Incorporated Areas Docket No.: FEMA–B–1911 and FEMA–B–2047	
City of Anamosa	City Hall, 107 South Ford Street, Anamosa, IA 52205.
City of Monticello	City Hall, 200 East 1st Street, Monticello, IA 52310.
City of Morley	City Hall, 507 Vine Street, Morley, IA 52312.
City of Olin	City Hall, 303 Jackson Street, Olin, IA 52320.
City of Oxford Junction	City Hall, 103 East Broadway Street, Oxford Junction, IA 52323.
City of Wyoming	City Hall, 141 West Main Street, Wyoming, IA 52362.
Unincorporated Areas of Jones County	Jones County Engineer's Office, 19501 Highway 64, Anamosa, IA 52205.
Forrest County, Mississippi and Incorporated Areas Docket No.: FEMA–B–2007	
City of Hattiesburg	City Hall, 200 Forrest Street, Hattiesburg, MS 39401.
City of Petal	Building Department, 101 West 8th Avenue, Petal, MS 39465.
Unincorporated Areas of Forrest County	Forrest County Chancery Building, 641 Main Street, Hattiesburg, MS 39401.
Greene County, Mississippi and Incorporated Areas Docket No.: FEMA–B–2007	
Town of McLain	Town Hall, 106 South Church Avenue, McLain, MS 39456.
Unincorporated Areas of Greene County	Greene County Emergency Management, 401 McInnis Avenue, Leakesville, MS 39451.
Jones County, Mississippi and Incorporated Areas Docket No.: FEMA–B–2007	
City of Ellisville	City Hall, 110 North Court Street, Ellisville, MS 39437.
City of Laurel	City Hall, 401 North 5th Avenue, Laurel, MS 39440.

Community	Community map repository address
Unincorporated Areas of Jones County	Jones County Circuit Court, 415 North 5th Avenue, Laurel, MS 39440.
Perry County, Mississippi and Incorporated Areas Docket No.: FEMA–B–2007	
Town of Richton	City Hall, 206 Dogwood Avenue East, Richton, MS 39476.
Unincorporated Areas of Perry County	Perry County Board of Supervisors Administration Building, 101 Main Street, New Augusta, MS 39462.
Clinton County, Ohio and Incorporated Areas Docket No.: FEMA–B–2031	
City of Wilmington	Municipal Building, 69 North South Street, Wilmington, OH 45177.
Unincorporated Areas of Clinton County	Clinton County Engineer, 1326 Fife Avenue, Wilmington, OH 45177.
Village of Blanchester	Municipal Building, 318 East Main Street, Blanchester, OH 45107.
Highland County, Ohio and Incorporated Areas Docket No.: FEMA–B–2031	
Unincorporated Areas of Highland County	Highland County Commissioners Office, 119 Governor Foraker Place, Suite 211, Hillsboro, OH 45133.
Village of Lynchburg	Village Hall, 155 South Main Street, Lynchburg, OH 45142.
Salt Lake County, Utah and Incorporated Areas Docket No.: FEMA–B–2000	
City of Bluffdale	City Hall, 2222 West 14400 South, Bluffdale, UT 84065.
City of Draper	City Hall, 1020 East Pioneer Road, Draper, UT 84020.
City of Herriman City	City Hall, 5355 West Herriman Main Street, Herriman City, UT 84096.
City of Millcreek	City Hall, 3330 South 1300 East, Millcreek, UT 84106.
City of Riverton	City Hall, 12830 South Redwood Road, Riverton, UT 84065.
City of Salt Lake City	Engineering Division, 349 South 200 East, Suite 600, Salt Lake City, UT 84111.
City of Sandy City	Public Utilities, 10000 Centennial Parkway, Suite 241, Sandy City, UT 84070.
Unincorporated Areas of Salt Lake County	Salt Lake County Public Works, Engineering, 2001 South State Street, Suite N3–120, Salt Lake City, UT 84190.

[FR Doc. 2021–16439 Filed 7–30–21; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2021–0014; OMB No. 1660–0070]

Agency Information Collection Activities: Submission for OMB Review; Comment Request; National Fire Department Registry

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of revision and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public to take this opportunity to comment on a revision of a currently approved collection. In accordance with the Paperwork Reduction Act of 1995, this notice seeks comments concerning the National Fire Department Registry and the collection of information related to fire departments such as addresses, total number of departments, number of stations per department, and number of firefighters. The U.S. Fire Administration (USFA) maintains the registry for the purpose of disseminating fire safety and prevention information to fire departments across the country.

DATES: Comments must be submitted on or before September 1, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, email address *FEMA-Information-Collections-Management@fema.dhs.gov* or Gayle Kelch, Statistician, FEMA, United States Fire Administration, National Fire Data Center at (301) 447–1154 or email *gayle.kelch@fema.dhs.gov.*

SUPPLEMENTARY INFORMATION: This proposed information collection previously published in the **Federal Register** on April 27, 2021, at 86 FR 22235 with a 60-day public comment period. No comments were received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: National Fire Department Registry.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: 1660–0070.

FEMA Forms: FEMA Form FF–USFA–FY–21–100—Paper Version (formerly FEMA Form 070–0–0–1); FEMA Form FF–USFA–FY–21–110—Online Version (formerly the screenshots of FEMA Form 070–0–0–1).

Abstract: This collection seeks to identify fire departments in the United

States to compile a database related to their demographics, capabilities, and activities. The database is used to guide programmatic decisions and provide information to the public and the fire service.

Affected Public: State, local or tribal government.

Estimated Number of Respondents: 6,370.

Estimated Number of Responses: 6,370.

Estimated Total Annual Burden Hours: 1,293.

Estimated Total Annual Respondent Cost: $9,961.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $55,573.

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.

Millicent L. Brown,

Senior Manager, Records Management Branch, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2021–16400 Filed 7–30–21; 8:45 am]

BILLING CODE 9111–76–P

DEPARTMENT OF HOMELAND SECURITY

[Docket Number DHS–2021–0024]

DHS Individual Complaint of Employment Discrimination, DHS Form 3090–1

AGENCY: Department of Homeland Security, (DHS).

ACTION: 30-Day notice and request for comments; extension without change of a currently approved collection, 1610–0001.

SUMMARY: The Department of Homeland Security, 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. DHS previously published this information collection request (ICR) in the **Federal Register** on Friday, May 21, 2021 for a 60-day public comment period. There were no public comments received by DHS. The purpose of this notice is to allow additional 30-days for public comments.

DATES: Comments are encouraged and will be accepted until September 1, 2021. This process is conducted in accordance with 5 CFR 1320.1.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

SUPPLEMENTARY INFORMATION: Explain the circumstances that make the collection of information necessary. Identify any legal or administrative requirements that necessitate the collection. Attach a copy of the appropriate section of each statute and regulation mandating or authorizing the collection of information.

It is the policy of the Government of the United States to provide equal opportunity in employment for all persons, to prohibit discrimination in employment because of race, color, religion, sex (including pregnancy, gender identity, and sexual orientation), national origin, age, disability, protected genetic information, or status as a parent, and to promote the full realization of equal employment opportunity (EEO) through a continuing affirmative program in each agency.

Persons who claim to have been subjected to these types of discrimination, or to retaliation for opposing these types of discrimination or for participating in any stage of administrative or judicial proceedings relating to them, can seek a remedy under Title VII of the Civil Rights Act (Title VII) (42 U.S.C. 2000e *et seq.*) (race, color, religion, sex (including pregnancy, gender identity, and sexual orientation), national origin), the Age Discrimination in Employment Act (ADEA) (29 U.S.C. 621 *et seq.*) (age), the Equal Pay Act (29 U.S.C. 206(d)) (sex), the Rehabilitation Act (29 U.S.C. 791 *et seq.*) (disability), the Genetic Information Nondiscrimination Act (GINA) (42 U.S.C. 2000ff *et seq.*) (genetic information), and Executive Order 11478 (as amended by Executive Orders 13087 and 13152) (sexual orientation or status as a parent).

The Department of Homeland Security (DHS), Office for Civil Rights and Civil Liberties (CRCL) adjudicates discrimination complaints filed by current and former DHS employees, as well as applicants for employment at DHS. The complaint adjudication process for statutory rights is outlined in the Equal Employment Opportunity Commission (EEOC) regulations found at Title 29, Code of Federal Regulations, Part 1614, and EEOC Management Directive 110. For complaints alleging discrimination prohibited by Executive Order 11478, DHS follows procedures similar to the procedures for statutory rights, to the extent permitted by law.

The recordkeeping provisions are designed to ensure that a current employee, former employee, or applicant for employment claiming to be aggrieved, or that person's attorney, provides a signed statement that is sufficiently precise to identify the aggrieved individual and the agency, and to describe generally the action(s) or practice(s) that form the basis of the complaint. The complaint must also contain a telephone number, email address, and address where the complainant or the representative can be contacted. The complaint form is used for original allegations of discrimination and for amendments to pending complaints of discrimination. The form also determines whether the person is willing to participate in mediation or other available types of alternative dispute resolution (ADR) to resolve the complaint; Congress has enacted legislation to encourage the use of ADR in the federal sector, and the form ensures that such an option is considered at this preliminary stage of the EEO complaint process.

A complainant may access the complaint form on the agency website and may submit a completed complaint form electronically to the relevant Component's EEO Office. The complaint form can then be directly uploaded into the DHS EEO Enterprise Complaints Tracking System, also known as ''icomplaints.''

The burden of compliance with the information collection requirement does not impact small businesses or other small entities.

The information collection frequency specified in the DHS complaint form is the minimum amount necessary and

appropriate for the agency to determine whether the allegations should be accepted for investigation, dismissed due to procedural grounds, or partially accepted and partially dismissed.

Complainants are provided a Privacy Act statement noting the purposes and uses of the information collected. No assurance of confidentiality is provided, because the collection is governed by EEOC Management Directive 110, which provides that ''Once the complaint is filed, the complaint file, or part of it, may be shared only with those who are involved and need access to it. This includes the EEO Director, agency EEO officials, and possibly persons whom the aggrieved person has identified as being responsible for the actions that gave rise to the complaint. The complaint file is not a public document to be released outside the EEO complaint process. The identity of the aggrieved person does not remain confidential in the formal complaint process.'' EEOC Management Directive 110 provides that aggrieved persons be so informed by an EEO counselor prior to the initiation of a formal complaint.

There is a decrease in burden. The previous approval documentation mistakenly included the burden for Federal Employees. This error has been corrected, resulting in the reporting of a reduced annual burden.

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: Department of Homeland Security, (DHS).

Title: DHS Individual Complaint of Employment Discrimination, DHS Form 3090–1.

OMB Number: 1610–001.

Frequency: On Occasion.

Affected Public: Private Sector.

Number of Respondents: 136.

Estimated Time per Respondent: 1 Hour.

Total Burden Hours: 68.

Robert Dorr,

Executive Director, Business Management Directorate.

[FR Doc. 2021–16394 Filed 7–30–21; 8:45 am]

BILLING CODE 9112–FL–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6281–N–01]

Notice of Final Determination for the Sharing of Formula Area Data as the Result of Expansion of Formula Area

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, Housing and Urban Development (HUD).

ACTION: Notice.

SUMMARY: This notice advises the public of HUD's final determination to approve a Memorandum of Agreement (MOA) between the Kalispel Indian Community (KIC), Colville Indian Housing Authority (CIHA) and Spokane Indian Housing Authority (SIHA) to allocate Needs data under the Indian Housing Block Grant (IHBG) program. This MOA resulted from HUD's decision to include the balance of Pend Oreille, Spokane and Stevens counties in the state of Washington into the Formula Area of the KIC, creating overlapping Formula Areas for the KIC, CHIA and SIHA. Consistent with IHBG program regulations HUD is announcing its final determination to approve the MOA.

DATES: Effective Date: August 2, 2021.

FOR FURTHER INFORMATION CONTACT: Hilary Atkin, Director, Office of Grants Management, Office of Native American Programs, Department of Housing and Urban Development, 451 Seventh Street SW, Room 9166, Washington, DC 20410, telephone 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 Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: The Indian Housing Block Grant (IHBG) program allocation formula is authorized by section 302 of the Native American Housing Assistance and Self Determination Act of 1996 (25 U.S.C. 4101 *et seq.*) (NAHASDA). In accordance with program regulations at 24 CFR part 1000, funds appropriated by Congress for the IHBG program are made to eligible grant recipients by formula to ensure the equitable and fair distribution of funds. The formula has four components including Need. Need is calculated using the seven factors listed at 24 CFR 1000.324, each based on a tribe's formula area. Should a tribe's formula area overlap with one or more other Indian tribes, 24 CFR 1000.326 provides the procedure HUD will use to resolve issue.

On October 22, 2020, HUD informed the KIC, CHIA and SIHA of its preliminary decision to increase the formula area of the KIC to include the balance of Pend Oreille, Spokane and Stevens counties in the state of Washington. HUD's preliminary decision was based on the Department of the Interior's Near Reservation Area Designation (44 FR 154, August 8, 1979). As a result of this decision overlapping formula areas were created for the KIC, CHIA and SIHA.

Whenever tribes have overlapping formula area, the Needs data for all the individual areas for all tribes are combined and then apportioned among the tribes in the overlap. Section 1000.326(b) provides that tribes affected may develop their own method of partitioning the Needs data associated with their overlapping geographies. Consistent with 24 CFR 1000.302, HUD is required to notify the affected Indian tribes by certified mail and provided the tribes with opportunity to comment for a period of not less than 90 days. HUD met this requirement with its October 22, 2020, letter to the KIC, SIHA and CIHA.

By letter dated December 3, 2020, KIC transmitted a MOA dated November 3, 2020, and signed by KIC, CIHA, and SIHA that outlined an alternative method of sharing data. The MOA provides that the KIC and SIHA will receive double their Tribal enrollment as their proportional share of the Needs component and the CIHA will receive as its proportional share, the remaining Needs portion. The formula area to be shared consists of the Reservation and trust lands of the three Tribes plus the balance of Douglas, Ferry, Lincoln, Okanogan, Pend Oreille, Spokane, and Stevens counties, all in the State of Washington. Finally, the MOA states that the agreement covers the period FY 2021 through FY 2025 unless it is terminated by any of the Tribes or extended by agreement of all Tribes. Absent any further notification from the Tribes, HUD will share Needs associated with the geographies listed above based on the method and time-period outlined in the MOA. HUD will resume allocating such Needs data based on

Total Resident Service Area Indian Population in FY 2026 unless further notification.

Consistent with 24 CFR 1000.302, HUD must consider all comments on its preliminary determination and publish the notice of final determination in the **Federal Register**. Consequently, this notice provides final determination that HUD is accepting the Tribe's MOA.

Dominique Blom,

General Deputy Assistant Secretary for Public and Indian Housing.

[FR Doc. 2021–16388 Filed 7–30–21; 8:45 am]

BILLING CODE 4210–67–P

INTER-AMERICAN FOUNDATION

Sunshine Act Meetings

TIME AND DATE: August 3, 2021, 2:00 p.m.–3:30 p.m.

PLACE: Via tele-conference.

STATUS: Meeting of the IAF Advisory Council, open to the public.

MATTERS TO BE CONSIDERED:

- Call to order
- IAF President/CEO Report
- Management Team Updates
- Adjournment

Portion to be Closed to the Public:

- Executive session closed to the public as provided for by 22 CFR 1004.4(b)

CONTACT PERSON FOR MORE INFORMATION: Aswathi Zachariah, General Counsel, (202) 683–7118.

For Dial-in Information Contact: Karen Vargas, Board Liaison, (202) 524–8869.

The Inter-American Foundation is holding this meeting under the Government in the Sunshine Act, 5 U.S.C. 552(b).

Aswathi Zachariah,

General Counsel.

[FR Doc. 2021–16486 Filed 7–29–21; 11:15 am]

BILLING CODE 7025–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLCO–923000.L1440000.ET0000; COC–25845]

Notice of Proposed Withdrawal and Opportunity for Public Meeting for the McPhee Dam and Reservoir, Dolores Project; Colorado

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of proposed withdrawal.

SUMMARY: The Secretary of the Interior, as requested by the Bureau of Reclamation (BOR), proposes to withdraw 953.06 acres of public lands from settlement, sale, location, or entry, under all of the general land laws, including the mining laws, and 309.56 acres of National Forest System lands from location and entry under the mining laws, and reserve them for use by the BOR in connection with the McPhee Dam and Reservoir, for a period of 100 years. This notice advises the public of an opportunity to comment on the withdrawal and to request a public meeting.

DATES: Comments and requests for a public meeting must be received by November 1, 2021.

ADDRESSES: All comments and meeting requests should be sent to the Bureau of Land Management (BLM) Colorado State Director, 2850 Youngfield Street, Lakewood, CO 80215.

FOR FURTHER INFORMATION CONTACT: John Beck, Chief, Branch of Lands and Realty, BLM Colorado State Office, telephone: 303–239–3882, email: *jbeck@blm.gov.* Persons who use a telecommunications device for the deaf (TDD) may call the Federal Relay Service (FRS) at 1–800–877–8339 to contact Mr. Beck during normal business hours. The FRS is available 24 hours a day, 7 days a week, to leave a message or question. You will receive a reply during normal business hours.

SUPPLEMENTARY INFORMATION: The McPhee Dam and Reservoir was previously withdrawn under Public Land Order (PLO) No. 5811 and extended by PLO No. 7473, which expired on January 21, 2021. The purpose of this withdrawal is to reserve the lands for and the protection for the McPhee Dam and Reservoir, Dolores Project, and capital investments.

The BOR has filed a petition/application for a new withdrawal for a 100-year term. Publication of this notice segregates the proposed withdrawal of 953.06 acres of public lands subject to valid existing rights, from settlement, sale, location, or entry under all of the general land laws, including the mining laws, and 309.56 acres of national forest system lands from location and entry under the mining laws, for up to 2 years.

Public Lands

New Mexico Principal Meridian, Colorado

T. 38 N., R. 15 W.,
Sec. 18, lots 2 and 3, and NE¼SW¼;
Sec. 19, SE¼NW¼ and NE¼SW¼.
T. 38 N., R. 16 W.,
Sec. 2, lots 1 thru 4;
Sec. 11, S½NE¼ and S½NW¼;
Sec. 12, SW¼NE¼, S½NW¼, N½SW¼, SW¼SW¼, N½SE¼, and SE¼SE¼;
Sec. 13, W½NW¼.

The areas aggregate 953.06 acres in Montezuma County.

San Juan National Forest

New Mexico Principal Meridian, Colorado

T. 38 N., R. 15 W.,
Sec. 3, lot 2, E½NE¼SE¼, SW¼NE¼SE¼, and SW¼SE¼;
Sec. 7, S½NE¼ and E½SE¼;
Sec. 28, NW¼SW¼.

The areas aggregate 309.56 acres in Montezuma County.

The total area contains 1,262.62 acres.

The use of a right-of-way, interagency, or cooperative agreement would not constrain nondiscretionary uses.

There are no suitable alternative sites in the area for a reservoir and dam.

No additional water rights are needed to fulfill the purpose of this withdrawal.

Comments, including name and street address of respondents, will be available for public review at the BLM Colorado State Office, 2850 Youngfield Street, Lakewood, CO 80215, during regular business hours 8:00 a.m. to 4:30 p.m., Monday through Friday, except holidays.

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 personally identifying information—may be made publicly available at any time. While you may ask the BLM in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting on this withdrawal must submit a written request to the State Director, BLM Colorado State Office at the address in the **ADDRESSES** section earlier. If the authorized officer determines that a public meeting will be held, a notice of the date, time, and place will be published in the **Federal Register** and local newspapers having general circulation in the vicinity of the land and also posted on the BLM website at: *www.blm.gov* at least 30 days before the scheduled date of the meeting.

For a period until August 2, 2023, subject to valid existing rights, the 953.06 acres of public lands are segregated from settlement, sale, location, or entry, under all of the general land laws, including the mining laws, and 309.56 acres of National Forest System lands are segregated from location and entry under the mining laws, unless the application is denied or canceled, or the withdrawal is approved

prior to that date. The temporary land uses which may be permitted during this segregative period include licenses, permits, rights-of-way, and disposal of mineral and vegetative resources other than under the mining laws.

(Authority: 43 CFR 2310.3–1)

Jamie Connell,

State Director.

[FR Doc. 2021–16386 Filed 7–30–21; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NRSS–EQD–SSB–NPS0027122; PX.XCOMP0134.00.1; 0MB Control Number 1024–NEW]

Agency Information Collection Activities; National Park Service Recreation Fee Pricing Survey

AGENCY: National Park Service, Interior.

ACTION: Notice of information collection; request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, we, the National Park Service (NPS) are proposing a new information collection.

DATES: Interested persons are invited to submit comments on or before October 1, 2021.

ADDRESSES: Send your comments on this information collection request (ICR) by mail to Phadrea Ponds, NPS Information Collection Clearance Officer, by email at *phadrea_ponds@nps.gov.* Please reference Office of Management and Budget (OMB) Control Number 1024–NEW (RECFEE) in the subject line of your comments.

FOR FURTHER INFORMATION CONTACT: To request additional information about this ICR, contact Bret Meldrum, Chief, Social Science Program, at *bret_meldrum@nps.gov* (email); or 970–267–7295 (phone). Please reference OMB Control Number 1024–NEW (RECFEE) in the subject line of your comments. Individuals who are hearing or speech impaired may call the Federal Relay Service at 1–800–877–8339 for TTY assistance.

SUPPLEMENTARY INFORMATION: In accordance with the Paperwork Reduction Act of 1995 (PRA, 44 U.S.C. 3501 *et seq.)* and 5 CFR 1320.8(d)(1), all information collections require approval under the PRA. As part of our continuing effort to reduce paperwork and respondent burdens, we invite the public and other Federal agencies to comment on new, proposed, revised, and continuing collections of information. This helps us assess the impact of our information collection requirements and minimize the public's reporting burden. It also helps the public understand our information collection requirements and provide the requested data in the desired format.

We are especially interested in public comment addressing the following:

(1) Whether or not the collection of information is necessary for the proper performance of the functions of the agency, including whether or not the information will have practical utility.

(2) The accuracy of our estimate of the burden for this 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.

(4) How might the agency 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 response.

Comments that you submit in response to this notice are a matter of public record. We will include or summarize each comment in our request to OMB to approve this ICR. 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.

Abstract: The NPS is authorized by the Federal Lands Recreation Enhancement Act (FLREA; 16 U.S.C. 6801–6814) to collect and retain recreation fees, including entrance fees and amenity fees for certain facilities, equipment, and services (such as campgrounds). Recreation fees collected under FLREA are used for a variety of projects that enhance the visitor experience. The NPS is also mandated by 54 U.S.C. 100701 and 100702 to provide state-of-the-art management, protection, and interpretation of, and research on, the resources of the System that is enhanced by the availability and utilization of a broad program of the highest quality science and information.

The NPS intends to pilot test a general population survey of recent and potential park visitors to evaluate behavior under different entrance fee pricing models. The proposed information collection will inform the design and administration of a future survey that is intended to help determine revenue and access implications of different entrance fee rates and collection models. The pilot study options will include explorations in, at minimum—increases in entrance fees, different fee structures, and technology-based solutions for collecting entrance fees to make the entrance process more convenient and efficient for visitors.

The first step in the process is to create and pretest survey questions. A pretest will be conducted to (1) validate the survey questions, (2) investigate various sampling methods, (3) estimate the respondent burden, and (4) determine the usability of the survey design. Following the pretest, a pilot survey will be administered nationwide to a sample of recent and potential park visitors. The pilot survey will be used to evaluate how visitors might respond to hypothetical questions regarding changes in entrance fees, fee structures, and technology-based solutions for collecting entrance fees. The pilot is designed to understand the effectiveness of the instrument and the response rates for the eventual final survey. A preliminary analysis of these results will demonstrate how different entrance fee rates and collection modes could affect revenue and visitor access. The data will allow the NPS to understand the degree of interest and methods-based considerations for a comprehensive study on fees with the intent of making more transparent and science-informed pricing decisions in the future.

Title of Collection: National Park Service Recreation Fee Pricing Survey.

OMB Control Number: 1024–NEW.

Form Number: None.

Type of Review: New.

Respondents/Affected Public: Individuals/households.

Respondent's Obligation: Voluntary.

Frequency of Collection: One-time.

Total Estimated Annual Nonhour Burden Cost: None.

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 authority for this action is the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Phadrea Ponds,

Information Collection Clearance Officer, National Park Service.

[FR Doc. 2021–16411 Filed 7–30–21; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1199]

Certain Tobacco Heating Articles and Components Thereof; Commission Determination To Review in Part a Final Initial Determination Finding a Violation of Section 337; Schedule for Filing Written Submissions on Issues Under Review and on Remedy, Public Interest, and Bonding

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (''Commission'') has determined to review in part a final initial determination (''FID'') of the presiding administrative law judge (''ALJ'') finding a violation of section 337 of the Tariff Act of 1930, as amended, in the above-captioned investigation. The Commission requests briefing from the parties on certain issues under review, as indicated in this notice. The Commission also requests briefing from the parties, interested government agencies, and interested persons on the issues of remedy, the public interest, and bonding.

FOR FURTHER INFORMATION CONTACT: Lynde Herzbach, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–3228. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On May 15, 2020, the Commission instituted this investigation under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337 (''section 337''), based on a complaint filed by RAI Strategic Holdings, Inc., R.J. Reynolds Vapor Company, and R.J. Reynolds Tobacco Company, all of Winston-Salem, North Carolina (collectively, ''Complainants''). *See* 85 FR 29482–83. The complaint, as supplemented, alleges a violation of section 337 based upon the importation of certain tobacco heating articles and components thereof by reason of infringement of certain claims of U.S. Patent Nos. 9,839,238 (''the '238 patent''); 9,930,915 (''the '915 patent''); 9,901,123 (''the '123 patent) (collectively, ''the Asserted Patents''). The complaint also alleges the existence of a domestic industry. The notice of investigation names five respondents: Altria Client Services LLC, Altria Group, Inc. (''AGI''), and Philip Morris USA, Inc., all of Richmond, Virginia; Philip Morris International Inc. (''PMI'') of New York, New York; and Philip Morris Products S.A. of Neuchatel, Switzerland (collectively, ''Respondents''). *See id.* The Office of Unfair Import Investigations (''OUII'') is also a party to the investigation. *See id.*

The Commission previously terminated respondents AGI and PMI from the investigation based on Complainants' partial withdrawal of the complaint. *See* Order No. 24 (Dec. 14, 2020), *unreviewed by* Comm'n Notice (Jan. 5, 2021).

The Commission previously affirmed an initial determination finding that the economic prong is satisfied under section 337(a)(3)(A) (19 U.S.C. 1337(a)(3)(A)) with respect to the '238 and '915 patents and provided supplemental analysis. Order No. 35 (Jan. 19, 2021), *affirmed in part by* Comm'n Notice (Feb. 18, 2021). The Commission took no position on the finding that the economic prong was satisfied under section 337(a)(3)(B) (19 U.S.C. 1337(a)(3)(B)). *Id.*

On May 14, 2021, the presiding ALJ issued the FID on violation. The FID finds a violation of section 337 as to the '915 patent and the '123 patent by virtue of Respondents' infringement of claims 1–3 and 5 of the '915 patent and claims 27–30 of the '123 patent. The FID finds that Complainants did not establish a violation with respect to the '238 patent. In particular, the FID finds that Respondents failed to show that the asserted claims of the '915 and '123 patents are invalid. The ID further finds that claim 19 of the '238 patent is invalid as anticipated. The FID finds that the domestic industry requirement is satisfied for each of the Asserted Patents.

The Recommended Determination on Remedy and Bond (''RD'') recommends the issuance of a limited exclusion order barring entry of products that infringe the asserted claims of the Asserted Patents. The RD does not recommend issuing cease and desist orders. The RD recommends imposing no bond during the Presidential review period. Finally, the RD concludes that the public interest evidence does not weigh against entry of a remedy.

On May 28, 2021, Complainants, Respondents, and OUII each filed petitions for review of various aspect of the FID. Specifically, Complainants filed a petition for review of the FID's infringement and validity findings for the '238 patent. Respondents filed a petition for review that challenges aspects of the FID's construction of ''electrical energy source'' recited in claims 1 and 3 of the '915 patent. Respondents also petitioned for review of the FID's findings concerning infringement and invalidity with respect to the '915 and '123 patents, and the FID's domestic industry findings for the '123 patent. Respondents contingently petitioned for review of the constructions of ''pressure channel'' and ''air inlet channel'' recited in claim 19 of the '238 patent, as well as the FID's infringement findings based on the alleged incorrect claim constructions. OUII filed a petition for review of the constructions of ''pressure channel'' and ''air inlet channel'' recited in claim 19 of the '238 patent, and the FID's infringement findings based on the limitation ''spatially separated'' recited in claim 19.

On June 8, 2021, the parties filed their respective responses to the various petitions for review. That same day, Respondents filed a motion to strike-in-part Complainants' petition for review to the extent the petition sought review of the RD. On June 21, 2021, Complainants filed a response opposing the motion. OUII did not file a response.

Having examined the record of the investigation, including the FID, the petitions for review, and the responses thereto, the Commission has determined to review the FID in part, as follows.

As to the '915 patent, the Commission has determined to review the ALJ's construction of the limitation ''electrical energy source'' recited in asserted claims 1 and 3 and the FID's infringement, technical prong, and invalidity findings to the extent they may be affected by a modified claim construction.

As to the '123 patent, the Commission has determined to review the FID's obviousness and domestic industry findings, including whether Complainants have satisfied the economic prong of the domestic industry requirement.

As to the '238 patent, the Commission has determined to review the FID's infringement finding.

The Commission has determined not to review the remainder of the FID. The Commission denies Respondents' motion to strike-in-part Complainants' petition for review.

The parties are asked to provide additional briefing on the following issues:

With regard to the '915 patent, please address whether a construction of the term ''electrical energy source'' to mean ''receptacle that provides for transmission of electrical current from the power source to the heating member, where the receptacle is not limited to a structure that requires wiring or insertion,'' is supported by the intrinsic and extrinsic evidence. Also, please address whether this modified claim construction affects any other findings in the FID regarding the '915 patent such as infringement, domestic industry technical prong, or invalidity.

The parties are requested to brief only the discrete issues identified above, with reference to the applicable law and evidentiary record. The parties are not to brief any other issues on review, which have already been adequately presented in the parties' previous filings.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia,* (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843, Comm'n Op. at 7–10 (Dec. 1994). In particular, the written submissions should address any request for a cease and desist order in the context of recent Commission opinions, including those in *Certain Arrowheads with Deploying Blades and Components Thereof and Packaging Therefor,* Inv. No. 337–TA–977, Comm'n Op. (Apr. 28, 2017) and *Certain Electric Skin Care Devices, Brushes and Chargers Therefor, and Kits Containing the Same,* Inv. No. 337–TA–959, Comm'n Op. (Feb. 13, 2017). Specifically, if Complainants seek a cease and desist order against any respondent, the written submissions should respond to the following requests:

(1) Please identify with citations to the record any information regarding commercially significant inventory in the United States as to each respondent against whom a cease and desist order is sought. If Complainants also rely on other significant domestic operations that could undercut the remedy provided by an exclusion order, please identify with citations to the record such information as to each respondent against whom a cease and desist order is sought.

(2) In relation to the infringing products, please identify any information in the record, including allegations in the pleadings, that addresses the existence of any domestic inventory, any domestic operations, or any sales-related activity directed at the United States for each respondent against whom a cease and desist order is sought.

(3) Please discuss any other basis upon which the Commission could enter a cease and desist order.

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and/or cease and desist orders would have on: (1) The public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation. The submissions should include a discussion of the RD's findings on the public interest.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the issues identified in this notice. In addition, the parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding.

In their initial submissions, Complainants are also requested to identify the remedy sought and Complainants and OUII are requested to submit proposed remedial orders for the Commission's consideration. Complainants are further requested to state the dates that the Asserted Patents expire, to provide the HTSUS subheadings under which the accused products are imported, and to supply the identification information for all known importers of the products at issue in this investigation. The initial written submissions and proposed remedial orders must be filed no later than close of business on August 10, 2021. Reply submissions must be filed no later than the close of business on August 17, 2021. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337–TA–1199) in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf*). Persons with questions regarding filing should contact the Secretary, (202) 205–2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy Rules 201.6 and 210.5(e)(2) (19 CFR 201.6 & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) By the

Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The Commission vote for this determination took place on July 27, 2021.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: July 27, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–16374 Filed 7–30–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–539 and 731–TA–1280–1282 (Review)]

Heavy Walled Rectangular Welded Carbon Steel Pipes and Tubes from Korea, Mexico, and Turkey; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the countervailing duty order on imports of heavy walled rectangular welded carbon steel pipes and tubes from Turkey and of the antidumping duty orders on imports of heavy walled rectangular welded carbon steel pipes and tubes from Korea, Mexico, and Turkey would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted August 2, 2021. To be assured of consideration, the deadline for responses is September 1, 2021. Comments on the adequacy of responses may be filed with the Commission by October 15, 2021.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones (202–205–3358), 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 (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On September 13, 2016, the Department of Commerce (''Commerce'') issued antidumping duty orders on imports of heavy walled rectangular welded carbon steel pipes and tubes from Korea, Mexico, and Turkey (81 FR 62865), and a countervailing duty order on imports from Turkey (81 FR 62874). The Commission is conducting reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full reviews or expedited reviews. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Countries* in these reviews are Korea, Mexico, and Turkey.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined the *Domestic Like Product* as consisting of heavy walled rectangular welded carbon steel pipes and tubes that were coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, the Commission defined the *Domestic Industry* as all U.S. producers of heavy walled rectangular welded carbon steel pipes and tubes.

(5) The *Order Date* is the date that the antidumping and countervailing duty orders under review became effective. In these reviews, the *Order Date* is September 13, 2016.

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014),

73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is September 1, 2021. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is October 15, 2021. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 21–5–495, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

Information to be provided in response to this notice of institution: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise*, a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the countervailing and antidumping duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in § 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in § 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in each *Subject*

Country that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2020, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2020 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from each *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2020 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in each *Subject Country* since the *Order Date,* and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in each *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: July 26, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–16240 Filed 7–30–21; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–1535–1536 (Final)]

Methionine From Japan and Spain; Supplemental Schedule for the Final Phase of Anti-Dumping Duty Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

DATES: July 23, 2021.

FOR FURTHER INFORMATION CONTACT: Calvin Chang ((202) 205–3062), 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 (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: Effective February 24, 2021, the Commission established a general schedule for the conduct of the final phase of its investigations on methionine from France, Japan, and Spain [1] following a preliminary determination by the U.S. Department of Commerce (''Commerce'') that imports of methionine from France were being sold at less than fair value (''LTFV'').[2] Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of March 9, 2021 (86 FR 13585). In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission conducted its hearing through video conference on May 11, 2021. All persons who requested the opportunity were permitted to participate.

The Commission subsequently issued its final determination that an industry in the United States was materially injured by reason of imports of methionine provided for in subheadings 2930.40.00 and 2930.90.46 of the Harmonized Tariff Schedule of the United States (''HTSUS'') from France that have been found by Commerce to be sold in the United States at LTFV.[3]

Commerce has issued final affirmative antidumping duty determinations with respect to methionine from Japan and Spain.[4] Accordingly, the Commission currently is issuing a supplemental schedule for its antidumping duty investigations on imports of methionine from Japan and Spain.

This supplemental schedule is as follows: The deadline for filing supplemental party comments on Commerce's final antidumping duty determinations is August 6, 2021. Supplemental party comments may address only Commerce's final antidumping duty determinations regarding imports of methionine from Japan and Spain. These supplemental final comments may not contain new factual information and may not exceed five (5) pages in length. The supplemental staff report in the final phase of these investigations regarding subject imports from Japan and Spain will be placed in the nonpublic record on August 17, 2021; a public version will be issued thereafter.

For further information concerning these investigations see the Commission's notice cited above and the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and C (19 CFR part 207).

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Additional written submissions to the Commission, including requests pursuant to section 201.12 of the Commission's rules, shall not be accepted unless good cause is shown for accepting such submissions, or unless the submission is pursuant to a specific request by a Commissioner or Commission staff.

In accordance with sections 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the investigations must be served on all other parties to the investigations (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: These investigations are being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.21 of the Commission's rules.

By order of the Commission.

Issued: July 27, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–16375 Filed 7–30–21; 8:45 am]

BILLING CODE 7020–02–P

[1] 86 FR 13585, March 9, 2021.

[2] 86 FR 12627, March 4, 2021.

[3] 86 FR 35826, July 7, 2021.

[4] 86 FR 38983 and 86 FR 38985, July 23, 2021. The Commission investigations became staggered when Commerce postponed its final determinations regarding LTFV imports of methionine from Japan and Spain.

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–467 and 731–TA–1164–1165 (Second Review)]

Narrow Woven Ribbons With Woven Selvedge From China and Taiwan; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the countervailing duty order on imports of narrow woven ribbons with woven selvedge (''narrow woven ribbons'') from China and revocation of the antidumping duty orders on narrow woven ribbons from China and Taiwan would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted August 2, 2021. To be assured of consideration, the deadline for responses is September 1, 2021. Comments on the adequacy of responses may be filed with the Commission by October 15, 2021.

FOR FURTHER INFORMATION CONTACT: Lawrence Jones (202–205–3358), 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 (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On September 1, 2010, the Department of Commerce (''Commerce'') issued a countervailing duty order on imports of narrow woven ribbons from China (75 FR 53642) and antidumping duty orders on imports of narrow woven ribbons from China and Taiwan (75 FR 53632, as amended on September 17, 2010, 75 FR 56982). Following the first five-year reviews by Commerce and the Commission,

effective September 22, 2016, Commerce issued a continuation of the countervailing duty order for China and antidumping duty orders for China and Taiwan on imports of narrow woven ribbons (81 FR 65341). The Commission is now conducting a second review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full reviews or expedited reviews. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year review, as defined by the Department of Commerce.

(2) The *Subject Countries* in these reviews are China and Taiwan.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations and first five-year review determinations, the Commission defined a single *Domestic Like Product* consisting of narrow woven ribbons that are coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations and first five-year review determinations, the Commission defined the *Domestic Industry* as all U.S. producers of narrow woven ribbons.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is September 1, 2021. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is October 15, 2021. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-

based filings or paper copies of any electronic filings will be accepted until further notice.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 21–5–496, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

Information To Be Provided in Response to This Notice of Institution: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* As used below, the term ''firm'' includes any related firms.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise*, a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the countervailing duty order on imports of narrow woven ribbons from China and revocation of the antidumping duty orders on narrow woven ribbons from China and Taiwan on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in section 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2015.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2020, except as noted (report quantity data in square yards and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2020 (report quantity data in square yards and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from each *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2020 (report quantity data in square yards and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in each *Subject Country* after 2015, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in each *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: July 26, 2021.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2021–16239 Filed 7–30–21; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–877]

Bulk Manufacturer of Controlled Substances Application: AMRI Rensselaer, Inc.

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Notice of application.

SUMMARY: AMRI Rensselaer, Inc., has applied to be registered as a bulk manufacturer of basic class(es) of controlled substance(s). Refer to Supplemental Information listed below for further drug information.

DATES: Registered bulk manufacturers of the affected basic class(es), and applicants therefore, may file written comments on or objections to the issuance of the proposed registration on or before October 1, 2021. Such persons may also file a written request for a hearing on the application on or before October 1, 2021.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA **Federal Register** Representative/DPW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: In accordance with 21 CFR 1301.33(a), this is notice that on May 31, 2021, AMRI Rensselaer Inc., 33 Riverside Avenue, Rensselaer, New York 12144–2951, applied to be registered as a bulk manufacturer of the following basic class(es) of controlled substance(s):

Controlled substance	Drug code	Schedule
Marihuana	7360	I
Tetrahydrocannabinols	7370	I
Amphetamine	1100	II
Lisdexamfetamine	1205	II
Pentobarbital	2270	II
ANPP (4-Anilino-N-phenethyl-4-piperidine).	8333	II
Codeine	9050	II
Oxycodone	9143	II
Hydromorphone	9150	II
Hydrocodone	9193	II
Morphine	9300	II
Fentanyl	9801	II

The company plans to manufacture the above controlled substances as bulk active pharmaceutical ingredients (API) for use in product development and for distribution to its customers. In reference to drug codes 7360 (Marihuana), and 7370 (Tetrahydrocannabinols), the company plans to bulk manufacture these drugs as synthetic. No other activities for these drug codes are authorized for this registration.

William T. McDermott,

Assistant Administrator.

[FR Doc. 2021–16337 Filed 7–30–21; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1122–0027]

Agency Information Collection Activities; Proposed eCollection Requested; Extension of a Currently Approved Collection

AGENCY: Office on Violence Against Women, Department of Justice.

ACTION: 60-Day notice.

SUMMARY: The Office on Violence Against Women (OVW), Department of Justice, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until October 1, 2021.

FOR FURTHER INFORMATION CONTACT: Written comments and/or suggestion regarding the items contained in this notice, especially the estimated public burden and associated response time, should be directed to Cathy Poston, Office on Violence Against Women, at 202–514–5430 or *Catherine.poston@usdoj.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the

public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

(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 submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection:* Extension of a currently approved collection.

(2) *Title of the Form/Collection:* Semi-Annual Progress Report for Grantees from the Engaging Men and Youth Program.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:* Form Number: 1122–0027. U.S. Department of Justice, Office on Violence Against Women.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* The affected public includes the approximately 8 grantees of the Consolidated Grant Program to Address Children and Youth Experiencing Domestic and Sexual Assault and Engage Men and Boys as Allies (Consolidated Youth Program) who are implementing engaging men and youth projects. The Consolidated Youth Program creates a unique opportunity for communities to increase collaboration among non-profit victim service providers, violence prevention programs, and child and youth organizations serving victims ages 0–24. Additionally, it supports organizations and programs that promote boys' and men's role in combating violence against women and girls. Eligible applicants are nonprofit, nongovernmental entities, Indian tribes or tribal nonprofit organizations, and territorial, tribal or unit of local government entities.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond/reply:* It is estimated that it will take the approximately 8 respondents (grantees from the Consolidated Youth Program who are implementing engaging men and youth projects) approximately one hour to complete a semi-annual progress report.

The semi-annual progress report is divided into sections that pertain to the different types of grantee activities.

(6) Program grantees will only be required to complete the sections of the form that pertain to their own specific activities.

(7) *An estimate of the total public burden (in hours) associated with the collection:* The total annual hour burden to complete the data collection forms is 16 hours, that is 8 grantees completing a form twice a year with an estimated completion time for the form being one hour.

If additional information is required, contact: Melody Braswell, Deputy Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 3E, 405B, Washington, DC 20530.

Dated: July 27, 2021.

Melody Braswell,

Department Clearance Officer, PRA, U.S. Department of Justice.

[FR Doc. 2021–16355 Filed 7–30–21; 8:45 am]

BILLING CODE 4410–FX–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (BJA) Docket No. 1792]

Meeting of the Public Safety Officer Medal of Valor Review Board

AGENCY: Office of Justice Programs (OJP), Bureau of Justice Assistance (BJA), Justice.

ACTION: Notice of meeting.

SUMMARY: This is an announcement of a meeting of the Public Safety Officer Medal of Valor Review Board, primarily intended to consider nominations for the 2020–2021 Medal of Valor, and to make a limited number of recommendations for submission to the U.S. Attorney General. Additional issues of importance to the Board may also be discussed. The virtual meeting/conference call date and time is listed below.

DATES: September 20, 2021, 12:30 p.m. to 3:00 p.m. EDT.

ADDRESSES: This meeting will be held virtually using web conferencing technology. The public may hear the proceedings of this virtual meeting/conference call by registering with Gregory Joy at least seven (7) days in advance with Gregory Joy (contact information below).

FOR FURTHER INFORMATION CONTACT: Gregory Joy, Policy Advisor, Bureau of Justice Assistance, Office of Justice Programs, 810 7th Street NW, Washington, DC 20531, by telephone at (202) 514–1369, toll free (866) 859–2687, or by email at *Gregory.joy@usdoj.gov.*

SUPPLEMENTARY INFORMATION: The Public Safety Officer Medal of Valor Review Board carries out those advisory functions specified in 42 U.S.C. 15202. Pursuant to 42 U.S.C. 15201, the President of the United States is authorized to award the Public Safety Officer Medal of Valor, the highest national award for valor by a public safety officer.

This virtual meeting/conference call is open to the public to participate remotely. For security purposes, members of the public who wish to participate must register at least seven (7) days in advance of the meeting/conference call by contacting Mr. Joy.

Access to the virtual meeting/conference call will not be allowed without prior registration. Please submit any comments or written statements for consideration by the Review Board in writing at least seven (7) days in advance of the meeting date.

Gregory Joy,

Policy Advisor/Designated Federal Officer, Bureau of Justice Assistance.

[FR Doc. 2021–16413 Filed 7–30–21; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Workforce Information Advisory Council

AGENCY: Employment and Training Administration, Labor.

ACTION: Notice of three virtual meetings in August 2021.

SUMMARY: Notice is hereby given that the Workforce Information Advisory Council (WIAC or Advisory Council) will meet for three days, virtually. Information for public attendance at the virtual meetings will be posted at

www.dol.gov/agencies/eta/wioa/wiac/meetings several days prior to each meeting date. The meetings will be open to the public.

DATES: The meetings will take place August 19, 2021, August 24, 2021, and August 31, 2021. Each meeting will begin at 12:00pm EDT and conclude at approximately 4:00 p.m. EDT. Public statements and requests for special accommodations or to address the Advisory Council must be received one week prior to the relevant meeting date.

ADDRESSES: Information for public attendance at the virtual meetings will be posted at *www.dol.gov/agencies/eta/wioa/wiac/meetings* several days prior to each meeting date. If problems arise accessing the meetings, please contact Donald Haughton, Unit Chief in the Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, at 202–693–2784.

FOR FURTHER INFORMATION CONTACT: Steven Rietzke, Chief, Division of National Programs, Tools, and Technical Assistance, Employment and Training Administration, U.S. Department of Labor, Room C–4510, 200 Constitution Ave. NW, Washington, DC 20210; Telephone: 202–693–3912. Mr. Rietzke is the WIAC Designated Federal Officer.

SUPPLEMENTARY INFORMATION:

Background: These meetings are being held pursuant to Sec. 308 of the Workforce Innovation and Opportunity Act of 2014 (WIOA) (Pub. L. 113–128), which amends Sec. 15 of the Wagner-Peyser Act of 1933 (29 U.S.C. 491–2). The WIAC is a federal advisory committee of workforce and labor market information experts representing a broad range of national, State, and local data and information users and producers. The WIAC was established in accordance with provisions of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. App.) and will act in accordance with the applicable provisions of FACA and its implementing regulation at 41 CFR 102–3. The purpose of the WIAC is to provide recommendations to the Secretary of Labor (Secretary), working jointly through the Assistant Secretary for Employment and Training and the Commissioner of Labor Statistics, to address: (1) The evaluation and improvement of the nationwide workforce and labor market information (WLMI) system and statewide systems that comprise the nationwide system; and (2) how the Department and the States will cooperate in the management of those systems. These systems include programs to produce employment-related statistics and State and local workforce and labor market information.

The Department of Labor anticipates the WIAC will accomplish its objectives by: (1) Studying workforce and labor market information issues; (2) seeking and sharing information on innovative approaches, new technologies, and data to inform employment, skills training, and workforce and economic development decision making and policy; and (3) advising the Secretary on how the workforce and labor market information system can best support workforce development, planning, and program development. Additional information is available at *www.dol.gov/agencies/eta/wioa/wiac/meetings.*

Purpose: The WIAC is currently in the process of identifying and reviewing issues and aspects of the WLMI system and statewide systems that comprise the nationwide system and how the Department and the States will cooperate in the management of those systems. As part of this process, the Advisory Council meets to gather information and to engage in deliberative and planning activities to facilitate the development and provision of its recommendations to the Secretary in a timely manner.

Agenda: The agenda topics for this series of virtual meetings are: (1) Review and approve minutes from the previous meeting; (2) remarks and discussion with Department of Labor leadership or agency staff on role of WLMI in economic recovery; (3) review and discuss reports and recommendations from the three sub-committees—Unemployment Insurance Wage Records, Changing Nature of Work, and Funding for State/Local WLMI Capacity; (4) discuss potential areas for future recommendations; and (5) comment period for the general public. A detailed agenda will be available at *www.dol.gov/agencies/eta/wioa/wiac/meetings* shortly before the meetings commence.

The Advisory Council will open the floor for public comment at approximately 2:30 p.m. EST on each meeting date and last for approximately 10 minutes. However, that time may change at the WIAC Chair's discretion.

Attending the meetings: Members of the public who require reasonable accommodations to attend any of the meetings may submit requests for accommodations via email to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line ''August 2021 WIAC Meeting Accommodations'' by the date indicated in the **DATES** section. Please include a specific description of the accommodations requested and phone number or email address where you may be contacted if additional information is needed to meet your request.

Public statements: Organizations or members of the public wishing to submit written statements may do so by mailing them to the person and address indicated in the **FOR FURTHER INFORMATION CONTACT** section by the date indicated in the **DATES** section or transmitting them as email attachments in PDF format to the email address indicated in the **FOR FURTHER INFORMATION CONTACT** section with the subject line ''August 2021 WIAC Meeting Public Statements'' by the date indicated in the **DATES** section. Submitters may include their name and contact information in a cover letter for mailed statements or in the body of the email for statements transmitted electronically. Relevant statements received before the date indicated in the **DATES** section will be included in the record of each meeting. No deletions, modifications, or redactions will be made to statements received, as they are public records. Please do not include personally identifiable information in your public statement.

Requests to Address the Advisory Council: Members of the public or representatives of organizations wishing to address the Advisory Council should forward their requests to the contact indicated in the **FOR FURTHER INFORMATION CONTACT** section, or contact the same by phone, by the date indicated in the **DATES** section. Oral presentations will be limited to 10 minutes, time permitting, and shall proceed at the discretion of the WIAC Chair. Individuals with disabilities, or others who need special accommodations, should indicate their needs along with their request.

Suzan G. LeVine,

Principal Deputy Assistant Secretary, Employment and Training, Labor.

[FR Doc. 2021–16370 Filed 7–30–21; 8:45 am]

BILLING CODE 4510–FN–P

DEPARTMENT OF LABOR

Mine Safety and Health Administration

Affirmative Decisions on Petitions for Modification Granted in Whole or in Part

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Notice.

SUMMARY: The Federal Mine Safety and Health Act of 1977 and Title 30 of the Code of Federal Regulations govern the

application, processing, and disposition of petitions for modification of mandatory safety standards. Any mine operator or representative of miners may petition for an alternative method of complying with an existing safety standard. MSHA reviews the content of each submitted petition, assesses the mine in question, and ultimately issues a decision on the petition. This notice includes a list of petitions for modification that were granted after MSHA's review and investigation, between December 15, 2020, and June 30, 2021.

ADDRESSES: Copies of the final decisions are posted on MSHA's website at *https://www.msha.gov/regulations/rulemaking/petitions-modification*. The public may inspect the petitions and final decisions during normal business hours in MSHA's Office of Standards, Regulations, and Variances, 201 12th Street South, Suite 4E401, Arlington, Virginia 22202. All visitors are required to check in at the receptionist's desk in Suite 4E401.

FOR FURTHER INFORMATION CONTACT: Jessica D. Senk, Director, Office of Standards, Regulations, and Variances at 202–693–9440 (voice), *Senk.Jessica@dol.gov* (email), or 202–693–9441 (facsimile). [These are not toll-free numbers.]

SUPPLEMENTARY INFORMATION:

I. Introduction

Under section 101 of the Federal Mine Safety and Health Act of 1977, any mine operator or representative of miners may petition to use an alternative approach to comply with a safety standard. In response, the Secretary of Labor (Secretary) or his or her designee may modify the application of a mandatory safety standard to that mine if the Secretary determines that: (1) An alternative method exists that will guarantee no less protection for the miners affected than that provided by the standard; or (2) the application of the standard will result in a diminution of safety to the affected miners.

MSHA bases the final decision on the petitioner's statements, any comments and information submitted by interested persons, and a field investigation of the conditions at the mine. In some instances, MSHA may approve a petition for modification on the condition that the mine operator complies with other requirements noted in the decision. In other instances, MSHA may deny, dismiss, or revoke a petition for modification. In accordance with 30 CFR 44.5, MSHA publishes every final action granting a petition for modification.

II. Granted Petitions for Modification

On the basis of the findings of MSHA's investigation, and as designee of the Secretary, MSHA granted or partially granted the petitions for modification below. Since the previous **Federal Register** notice (86 FR 319) included petitions granted through December 14, 2020, listed below are petitions granted between December 15, 2020 and June 30, 2021. The granted petitions are shown in the order that MSHA received them.

- *Docket Number:* M–2019–057–C

  FR Notice: 84 FR 70569 (12/23/2019).

  Petitioner: Marfork Coal Company, LLC, P.O. Box 457, Whitesville, WV 25209.

  Mine: Black Eagle, MSHA I.D. No. 46–09550, located in Raleigh County, West Virginia.

  Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

- *Docket Number:* M–2019–058–C

  FR Notice: 85 FR 4709 (01/27/2020)

  Petitioner: Peabody Midwest Mining, LLC, 7100 Eagle Crest Blvd., Evansville, IN 47715.

  Mine: Francisco Underground Pit, MSHA I.D. No. 12–02295, located in Gibson County, IN.

  Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

- *Docket Number:* M–2019–059–C

  FR Notice: 85 FR 4709 (01/27/2020).

  Petitioner: Peabody Midwest Mining, LLC, 7100 Eagle Crest Blvd., Evansville, IN 47715.

  Mine: Francisco Underground Pit, MSHA I.D. No. 12–02295, located in Gibson County, IN.

  Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

- *Docket Number:* M–2019–060–C

  FR Notice: 85 FR 4709(01/27/2020).

  Petitioner: Peabody Midwest Mining, LLC, 7100 Eagle Crest Blvd., Evansville, IN 47715.

  Mine: Francisco Underground Pit, MSHA I.D. No. 12–02295, located in Gibson County, IN.

  Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

- *Docket Number:* M–2019–068–C

  FR Notice: 85 FR 29751 (05/18/2020).

  Petitioner: Peabody Twentymile Mining, LLC, 29515 Route County Road #27, Oak Creek, CO 80467.

  Mine: Foidel Creek Mine, MSHA I.D. No. 05–03836, located in Routt County, Colorado.

  Regulation Affected: 30 CFR 75.507–1(a) (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

- *Docket Number:* M–2019–069–C

  FR Notice: 85 FR 29751 (05/18/2020).

  Petitioner: Peabody Twentymile Mining, LLC, 29515 Route County Road #27, Oak Creek, CO 80467.

  Mine: Foidel Creek Mine, MSHA I.D. No. 05–03836, located in Routt County, Colorado.

  Regulation Affected: 30 CFR 75.1002(a) (Installation of electric equipment and conductors; permissibility).

- *Docket Number:* M–2020–005–C

  FR Notice: 85 FR 20528 (04/13/2020).

  Petitioner: Affinity Coal Company, 111 Affinity Complex Rd., Sophia, WV 25878.

  Mine: Affinity Mine, MSHA I.D. No. 46–08878, located in Raleigh County, West Virginia.

  Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

- *Docket Number:* M–2020–008–C

  FR Notice: 85 FR 47404 (08/05/2020).

  Petitioner: Century Mining LLC, 200 Chapel Brook Drive, Bridgeport, West Virginia 26330.

  Mine: Longview Mine, MSHA I.D. No. 46–09447, located in Barbour County, West Virginia.

  Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

- *Docket Number:* M–2020–010–C

  FR Notice: 85 FR 47404 (08/05/2020).

  Petitioner: Century Mining LLC, 200 Chapel Brook Drive, Bridgeport, West Virginia 26330.

  Mine: Longview Mine, MSHA I.D. No. 46–09447, located in Barbour County, West Virginia.

  Regulation Affected: 30 CFR 75.1700 (Oil and gas wells).

- *Docket Number:* M–2020–003–M

  FR Notice: 85 FR 58396 (09/18/2020).

  Petitioner: Solvay Chemicals, Inc., P.O. Box 1167, Green River, WY 82935.

  Mine: Solvay Chemicals, Inc., MSHA I.D. No. 48–01295, located in Sweetwater County, WY.

  Regulation Affected: 30 CFR 57.22305 (Approved equipment (III mines)).

- *Docket Number:* M–2020–022–C

  FR Notice: 85 FR 66582 (10/20/2020).

  Petitioner: Century Mining LLC, 200 Chapel Brook Drive, Bridgeport, West Virginia 26330.

  Mine: Longview Mine, MSHA I.D. No. 46–09447, located in Barbour County, West Virginia.

  Regulation Affected: 30 CFR 75.507–1 (Electric equipment other than power-

connection points; outby the last open crosscut; return air; permissibility requirements).

- *Docket Number:* M–2020–024–C

FR Notice: 85 FR 66582 (10/20/2020).

Petitioner: Century Mining LLC, 200 Chapel Brook Drive, Bridgeport, West Virginia 26330.

Mine: Longview Mine, MSHA I.D. No. 46–09447, located in Barbour County, West Virginia.

Regulation Affected: 30 CFR 75.1002 (Installation of electric equipment and conductors; permissibility).

- *Docket Number:* M–2020–029–C

FR Notice: 85 FR 70196 (11/04/2020).

Petitioner: Canyon Fuel Company, LLC, 597 South SR 24, Salina, UT 84654.

Mine: Sufco Mine, MSHA I.D. No. 42–00089, located in Sevier County, Utah.

Regulation Affected: 30 CFR 75.500 (Permissible electric equipment).

- *Docket Number:* M–2020–030–C

FR Notice: 85 FR 70196 (11/04/2020).

Petitioner: Canyon Fuel Company, LLC, 597 South SR 24, Salina, UT 84654.

Mine: Sufco Mine, MSHA I.D. No. 42–00089, located in Sevier County, Utah.

Regulation Affected: 30 CFR 75.507–1 (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

- *Docket Number:* M–2020–032–C

FR Notice: 85 FR 71661 (11/10/2020).

Petitioner: Canyon Fuel Company, LLC, HC 35 Box 380, Helper, UT 84526.

Mine: Skyline Mine, MSHA I.D. No. 42–01566, located in Carbon County, Utah.

Regulation Affected: 30 CFR 75.500(d) (Permissible electric equipment).

- *Docket Number:* M–2020–033–C

FR Notice: 85 FR 71661 (11/10/2020).

Petitioner: Canyon Fuel Company, LLC, HC 35 Box 380, Helper, UT 84526.

Mine: Skyline Mine, MSHA I.D. No. 42–01566, located in Carbon County, Utah.

Regulation Affected: 30 CFR 75.507–1 (Electric equipment other than power-connection points; outby the last open crosscut; return air; permissibility requirements).

- *Docket Number:* M–2021–001–C

FR Notice: 86 FR 11333 (02/24/2021).

Petitioner: Patton Mining LLC., 12051 9th Avenue, Hillsboro, Illinois 62049.

Mine: Deer Run Mine, MSHA I.D. No. 11–03182, located in Montgomery County, Illinois.

Regulation Affected: 30 CFR 75.1909 (Nonpermissible diesel-powered equipment; design and performance requirements).

Jessica Senk,

Director, Office of Standards, Regulations, and Variances.

[FR Doc. 2021–16369 Filed 7–30–21; 8:45 am]

BILLING CODE 4520–43–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: [21–049]]

Name of Information Collection: Generic Clearance for the NASA Office of STEM Engagement Performance Measurement and Evaluation (Testing)

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, 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.

DATES: Comments are due by September 1, 2021.

ADDRESSES: Written comments and recommendations for this information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.*

Find this information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Claire Little, NASA Clearance Officer, NASA Headquarters, 300 E Street SW, JF0000, Washington, DC 20546, 202–358–2375 or email *claire.a.little@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

NASA's founding legislation, the Space Act of 1958, as amended, directs the agency to expand human knowledge of Earth and space phenomena and to preserve the role of the United States as a leader in aeronautics, space science, and technology. The NASA Office of STEM Engagement administers the agency's national education activities in support of the Space Act, including the performance measurement and evaluation of educational projects and programs. This generic clearance will allow the NASA Office of STEM Engagement to continue to test and pilot with subject matter experts, secondary students, higher education students, educators, and interested parties new and existing information collection forms and assessment instruments for the purposes of improvement and establishing validity and reliability characteristics of the forms and instruments. Existing information collections include the NASA Intern Survey (Retrospective Survey), NASA Internship Applicants and Awardees Survey (Retrospective Survey), STEM Challenges Impact Surveys (Educator Feedback Retrospective Survey), STEM Challenges Impact Surveys (Parent Survey), and STEM Challenges Impact Surveys (Student Retrospective Survey). Forms and instruments to be tested include program application forms, customer satisfaction questionnaires, focus group protocols, and project activity survey instruments. Methodological testing will include focus group discussions, pilot surveys to test new individual question items as well as the complete form and instrument. In addition, test-retest and similar protocols will be used to determine reliability characteristics of the forms and instruments. Methodological testing will assure that forms and instruments accurately and consistently collect and measure what they are intended to measure and that data collection items are interpreted precisely and consistently, all towards the goal of accurate Agency reporting while improving the execution of NASA STEM Engagement activities.

II. Methods of Collection

Electronic, paper, and focus group interviews.

III. Data

Title: Generic Clearance for the NASA Office of Education Performance Measurement and Evaluation (Testing).

OMB Number: 2700–0159.

Type of Review: Renewal of an existing collection.

Affected Public: Individuals and Households.

Estimated Annual Number of Activities: 8.

Estimated Number of Respondents per Activity: 2,800.

Annual Responses: 1.

Estimated Time per Response: 15 minutes.

Estimated Total Annual Burden Hours: 5,600.

Estimated Total Annual Cost: $54,082.

IV. Request for Comments

Comments are invited on: (1) Whether the proposed collection of information

is necessary for the proper performance of the functions of NASA, including whether the information collected has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (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 automated collection techniques or the use of other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Authority: Paperwork Reduction Act of 1995.

Lori Parker,

NASA PRA Clearance Officer.

[FR Doc. 2021–16383 Filed 7–30–21; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2021–038]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: We have submitted a request to the Office of Management and Budget (OMB) for approval to continue to collect information from people who participate in the National Historical Publications and Records Commission (NHPRC) grant programs. Organizations requesting a grant from the NHPRC must submit certain information the NHPRC staff, reviewers, and the Commission use to determine if the applicant and proposed project are eligible for an NHPRC grant; if the request is recommended for approval, the prospective grantee provides additional information acknowledging the offer of the grant and regulatory requirements; and, grantees must respond to an accounting questionnaire designed to identify potential recipients with limited experience managing Federal funds and provide appropriate training or additional safeguards for Federal funds. We invite you to comment on the proposed information collections.

DATES: OMB must receive written comments on or before September 1, 2021.

ADDRESSES: Send any comments and recommendations on the proposed information collection in writing to *www.reginfo.gov/public/do/PRAMain.* You can find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Tamee Fechhelm, Paperwork Reduction Act Officer, by email at *tamee.fechhelm@nara.gob* or by telephone at 301.837.1694 with any requests for additional information.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite the public and other Federal agencies to comment on proposed information collections. We published a notice of proposed collection for these information collections on May 7, 2021 (86 FR 24670) and we received no comments. We are therefore submitting the described information collections to OMB for approval.

If you have comments or suggestions, they should address one or more of the following points: (a) Whether the proposed information collections are necessary for NARA to properly perform its functions; (b) our estimate of the burden of the proposed information collections and its accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether these collections affect small businesses.

In this notice, we solicit comments concerning the following information collections:

1. *Title:* National Historical Publications and Records Commission (NHPRC) Grant Program Budget Form and Instructions and NHPRC Grant Offer Acknowledgement.

OMB number: 3095–0013.

Agency form number: NA Form 17001 and 17001a.

Type of review: Regular.

Affected public: Nonprofit organizations and institutions, state and local government agencies, and Federally-acknowledged or state-recognized Native American tribes or groups, who apply for and receive NHPRC grants for support of historical documentary editions, archival preservation and planning projects, and other records projects.

Estimated number of respondents: 244 per year submit applications; approximately 25 grantees need to submit revised budgets.

Estimated time per response: 10 hours per application; five hours per revised budget.

Frequency of response: On occasion for the application; as needed for revised budget. Currently, the NHPRC considers grant applications two times per year. Respondents usually submit no more than one application per year, and, for those who need to submit revised budgets, only one revised budget per year.

Estimated total annual burden hours: 1,765 hours.

Abstract: The NHPRC posts grant announcements to their website and to *grants.gov* (*www.grants.gov*), where the information will be specific to the grant opportunity named. The basic information collection remains the same. The NA Form 17001 is used by the NHPRC staff, reviewers, and the Commission to determine if the applicant and proposed project are eligible for an NHPRC grant, and whether the proposed project is methodologically sound and suitable for support. The NA Form 17001a, NHPRC Grant Offer Acknowledgement, is used after the Archivist of the United States, as chair of the Commission, recommends a grant for approval. The prospective grantee must acknowledge the offer of the grant and agree to meet the requirements of applicable Federal regulations. In addition, they must verify the existence of an indirect cost agreement with a cognizant Federal agency if they are claiming indirect costs in the project's budget.

2. *Title:* Accounting System and Financial Capability Questionnaire.

OMB number: 3095–0072.

Agency form numbers: NA Form 17003.

Type of review: Regular.

Affected public: Not-for-profit institutions and state, local, or tribal government.

Estimated number of respondents: 75.

Estimated time per response: 4 hours.

Frequency of response: On occasion.

Estimated total annual burden hours: 300.

Abstract: Pursuant to Title 2, Section 215 of the Code of Federal Regulations, Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations (formerly OMB Circular A–110), and OMB Circular A–133, Audits of States, Local Governments, and Non-Profit Organizations, grant recipients are required to maintain adequate accounting controls and systems in managing and administering Federal funds. Some of the recipients of grants from the NHPRC have proven to have limited experience with managing

Federal funds. This questionnaire is designed to identify those potential recipients and provide appropriate training or additional safeguards for Federal funds. Additionally, the questionnaire serves as a pre-audit function in identifying potential deficiencies and minimizing the risk of fraud, waste, abuse, or mismanagement, which we use in lieu of a more costly and time consuming formal pre-award audit.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2021–16442 Filed 7–30–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–21–0010; NARA–2021–037]

Records Schedules; Availability and Request for Comments

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice of availability of proposed records schedules; request for comments.

SUMMARY: The National Archives and Records Administration (NARA) publishes notice of certain Federal agency requests for records disposition authority (records schedules). We publish notice in the **Federal Register** and on *regulations.gov* for records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on such records schedules.

DATES: NARA must receive comments by September 16, 2021.

ADDRESSES: You may submit comments by the following method. You must cite the control number, which appears on the records schedule in parentheses after the name of the agency that submitted the schedule.

- *Federal eRulemaking Portal: http://www.regulations.gov.*

Due to COVID–19 building closures, we are currently temporarily not accepting comments by mail. However, if you are unable to comment via *regulations.gov*, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

FOR FURTHER INFORMATION CONTACT: Kimberly Keravuori, Regulatory and External Policy Program Manager, by email at *regulation_comments@nara.gov.* For information about records schedules, contact Records Management Operations by email at *request.schedule@nara.gov,* by mail at the address above, or by phone at 301–837–1799.

SUPPLEMENTARY INFORMATION:

Public Comment Procedures

We are publishing notice of records schedules in which agencies propose to dispose of records they no longer need to conduct agency business. We invite public comments on these records schedules, as required by 44 U.S.C. 3303a(a), and list the schedules at the end of this notice by agency and subdivision requesting disposition authority.

In addition, this notice lists the organizational unit(s) accumulating the records or states that the schedule has agency-wide applicability. It also provides the control number assigned to each schedule, which you will need if you submit comments on that schedule.

We have uploaded the records schedules and accompanying appraisal memoranda to the *regulations.gov* docket for this notice as ''other'' documents. Each records schedule contains a full description of the records at the file unit level as well as their proposed disposition. The appraisal memorandum for the schedule includes information about the records.

We will post comments, including any personal information and attachments, to the public docket unchanged. Because comments are public, you are responsible for ensuring that you do not include any confidential or other information that you or a third party may not wish to be publicly posted. If you want to submit a comment with confidential information or cannot otherwise use the *regulations.gov* portal, you may contact *request.schedule@nara.gov* for instructions on submitting your comment.

We will consider all comments submitted by the posted deadline and consult as needed with the Federal agency seeking the disposition authority. After considering comments, we will post on *regulations.gov* a ''Consolidated Reply'' summarizing the comments, responding to them, and noting any changes we have made to the proposed records schedule. We will then send the schedule for final approval by the Archivist of the United States. You may elect at *regulations.gov* to receive updates on the docket, including an alert when we post the Consolidated Reply, whether or not you submit a comment. If you have a question, you can submit it as a comment, and can also submit any concerns or comments you would have to a possible response to the question. We will address these items in consolidated replies along with any other comments submitted on that schedule.

We will post schedules on our website in the Records Control Schedule (RCS) Repository, at *https://www.archives.gov/records-mgmt/rcs,* after the Archivist approves them. The RCS contains all schedules approved since 1973.

Background

Each year, Federal agencies create billions of records. To control this accumulation, agency records managers prepare schedules proposing retention periods for records and submit these schedules for NARA's approval. Once approved by NARA, records schedules provide mandatory instructions on what happens to records when no longer needed for current Government business. The records schedules authorize agencies to preserve records of continuing value in the National Archives or to destroy, after a specified period, records lacking continuing administrative, legal, research, or other value. Some schedules are comprehensive and cover all the records of an agency or one of its major subdivisions. Most schedules, however, cover records of only one office or program or a few series of records. Many of these update previously approved schedules, and some include records proposed as permanent.

Agencies may not destroy Federal records without the approval of the Archivist of the United States. The Archivist grants this approval only after thorough consideration of the records' administrative use by the agency of origin, the rights of the Government and of private people directly affected by the Government's activities, and whether or not the records have historical or other value. Public review and comment on these records schedules is part of the Archivist's consideration process.

Schedules Pending

1. Department of Commerce, National Institute of Standards and Technology, Ombuds Program Records (DAA–0167–2021–0001).

2. Department of Health and Human Services, National Institutes of Health, Peer Review Records (DAA–0443–2021–0001).

3. Department of Homeland Security, Federal Emergency Management

Agency, Trip Instruction and Assistance Reports (DAA–0311–2021–0002).

Laurence Brewer,

Chief Records Officer for the U.S. Government.

[FR Doc. 2021–16443 Filed 7–30–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA–2021–039]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: National Archives and Records Administration (NARA).

ACTION: Notice.

SUMMARY: We have submitted a request to the Office of Management and Budget (OMB) for approval to continue to collect information used by registrants or other authorized individuals to request information from or copies of Selective Service System (SSS) records. We invite you to comment on this proposed information collection.

DATES: OMB must receive written comments on or before September 1, 2021.

ADDRESSES: Send any comments and recommendations on the proposed information collection in writing to *www.reginfo.gov/public/do/PRAMain.* You can find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Tamee Fechhelm, Paperwork Reduction Act Officer, by email at *tamee.fechhelm@nara.gob* or by telephone at 301.837.1694 with any requests for additional information.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104–13), we invite the general public and other Federal agencies to comment on proposed information collections. We published a notice of proposed collection for this information collection on May 10, 2021 (86 FR 24900) and we received one comment. The commenter stated, ''I am a professional genealogist and I frequently research elusive individuals who lived in the 20th century. These selective service records are immensely useful, because they cover nearly all males, but they are very inaccessible because they can only be found if the individual's exact address is known. The form necessarily requires address, because that is how the records are organized. However, this impacts my ability to do my job because it renders the vital documents unusable if the registrant moved around and I cannot pinpoint exactly where he lived. I hope that NARA prioritizes either the indexing or digitization of these documents, so that they can be better utilized by the research community, thus not requiring the address to be known.''

We have considered this comment and provided a response to the commenter. Due to the size of the collection, we have no immediate plans to index the Records of the Selective Service System. However, a great number of the Draft Registration cards, including those from WWI (1917–1918) and WWII, have been digitized and are available online at ancestry.com, fold3.com, and familysearch.org (the latter two offer free memberships), which provide their own means of searching and tagging to aid people in finding the records. Once normal operations resume, records on ancestry.com can be viewed for free in National Archives Public Research Rooms with Public Access PCs. Prior to the pandemic, we discussed possibly digitizing the post-WWII Draft Registration cards, and hope to continue such discussions post-pandemic, once we resume normal operations. We appreciate the comment and will continue efforts to make records more accessible.

This comment does not change the purpose of the information collection or change the information we collect from researchers who are requesting access to archival records. We have therefore submitted the described information collection to OMB for approval. We will continue requesting as much record-identifying information from researchers as possible, pursuant to this information collection, to aid us in finding the documents researchers seek, including the SSS records this researcher mentions.

If you have comments or suggestions, they should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) our estimate of the burden of the proposed information collection and its accuracy; (c) ways we could enhance the quality, utility, and clarity of the information we collect; (d) ways we could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether this collection affects small businesses.

In this notice, we solicit comments concerning the following information collection:

Title: Selective Service System Record Request.

OMB number: 3095–0071.

Agency form numbers: NA Form 13172.

Type of review: Regular.

Affected public: Individuals or households.

Estimated number of respondents: 1,500.

Estimated time per response: 2 minutes.

Frequency of response: On occasion.

Estimated total annual burden hours: 50.

Abstract: The National Personnel Records Center (NPRC) of the National Archives and Records Administration (NARA) administers the Selective Service System (SSS) records. The SSS records contain both classification records and registration cards of registrants born before January 1, 1960. When registrants or other authorized individuals request information from or copies of SSS records they must provide on forms or letters certain information about the registrant and the nature of the request. Requesters use NA Form 13172, Selective Service Record Request to obtain information from SSS records stored at NARA facilities.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2021–16444 Filed 7–30–21; 8:45 am]

BILLING CODE 7515–01–P

NATIONAL SCIENCE FOUNDATION

Sunshine Act Meetings

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: 86 FR 40216, July 27, 2021.

PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING: The National Science Board's Committee on External Engagement teleconference meeting was scheduled for August 3, 2021, from 11:00–11:45 a.m. EDT.

CHANGES IN THE MEETING: The new date and time is July 30, 2021, from 5:30–6:15 p.m. EDT.

CONTACT PERSON FOR MORE INFORMATION: Chris Blair, 703/292–7000, *cblair@nsf.gov.*

Chris Blair,

Executive Assistant to the National Science Board Office.

[FR Doc. 2021–16496 Filed 7–29–21; 4:15 pm]

BILLING CODE P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0220]

Seismic Design Classification for Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory guide; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 6 to Regulatory Guide (RG) 1.29, ''Seismic Design Classification for Nuclear Power Plants.'' This RG describes a method that the staff of the NRC considers acceptable for use in identifying and classifying those features of light-water-reactor nuclear power plants that must be designed to withstand the effects of the safe-shutdown earthquake. Revision 6 corrects a minor error in the numbering of the elements in Section C, ''Staff Regulatory Guidance.''

DATES: RG 1.29 is available on August 2, 2021.

ADDRESSES: Please refer to Docket ID NRC–2015–0220 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2015–0220. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, 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 (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

Revision 6 to RG 1.29 and the regulatory analysis may be found in ADAMS under Accession Nos. ML21155A003 and ML21155A004, respectively.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Yuken Wong, Office of Nuclear Reactor Regulation, telephone: 301–415–0500, email: *Yuken.Wong@nrc.gov* and Edward O'Donnell, Office of Nuclear Regulatory Research, telephone: 301–415–3317, email: *Edward.Odonnell@nrc.gov.* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

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 regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses.

II. Additional Information

RG 1.29, Revision 6 corrects a minor error in the numbering within the Section C, ''Staff Regulatory Guidance.'' What was C.1.i became C.2. This results in C.2 becoming C.3 and C.3 became C.4. In addition, RG 1.29 was reformatted to conform with the current template for Regulatory Guides.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting and Issue Finality

Issuance of RG 1.29 does not constitute backfitting as defined in Section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; constitute forward fitting as that term is defined and described in MD 8.4; or affect issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certificates, and Approvals for Nuclear Power Plants.'' As explained in this regulatory guide, applicants and licensees would not be required to comply with the positions set forth in this RG.

Dated: July 27, 2021.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2021–16343 Filed 7–30–21; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2021–0147]

Evaluations of Explosions Postulated To Occur at Nearby Facilities and on Transportation Routes Near Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft regulatory guide; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing for public comment draft regulatory guide (DG)–1388, ''Evaluations of Explosions Postulated to Occur at Nearby Facilities and on Transportation Routes Near Nuclear Power Plants.'' This DG is proposed Revision 3 to Regulatory Guide (RG) 1.91. RG 1.91 describes methods that the NRC finds acceptable for applicants and licensees of nuclear power reactors to use in evaluating postulated accidental explosions at nearby facilities and transportation routes.

DATES: Submit comments by September 1, 2021. Comments received after this date will be considered if it is practical to do so, but the NRC is able to ensure consideration only for comments received on or before this date. Although a time limit is given, comments and suggestions in connection with items for inclusion in guides currently being developed or improvements in all published guides are encouraged at any time.

ADDRESSES: You may submit comments by any of the following methods; however, the NRC encourages electronic comment submission through the Federal Rulemaking website:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0147. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical

questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

• *Mail comments to:* Office of Administration, Mail Stop: TWFN–7–A60M, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, ATTN: Program Management, Announcements and Editing Staff.

For additional direction on obtaining information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Michael Eudy, Office of Nuclear Regulatory Research, telephone: 301–415–3104, email: *Michael.Eudy@nrc.gov,* Ronaldo Jenkins, Office of Nuclear Regulatory Research, telephone: 301–415–6978, email: *Ronaldo.Jenkins@nrc.gov,* and Kenneth See, Office of Nuclear Reactor Regulation, telephone: 301–415–1508, email: *Kenneth.See@nrc.gov.* They are all staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2021–0147 when contacting the NRC about the availability of information for this action. You may obtain publicly available information related to this action by any of the following methods:

• *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2021–0147.

• *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, 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 (if it is available in ADAMS) is provided the first time that it is mentioned in this document.

• *Attention:* The PDR, where you may examine and order copies of public documents, is currently closed. You may submit your request to the PDR via email at *pdr.resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8:00 a.m. and 4:00 p.m. (ET), Monday through Friday, except Federal holidays.

B. Submitting Comments

The NRC encourages electronic comment submission through the Federal Rulemaking website (*https://www.regulations.gov*). Please include Docket ID NRC–2021–0147 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC will post all comment submissions at *https://www.regulations.gov* as well as enter the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Additional Information

The NRC is issuing for public comment a DG in the NRC's ''Regulatory Guide'' series. This series was developed to describe, and make available to the public, information regarding 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 issues or postulated events, and data that the staff needs in its review of applications for permits and licenses.

This proposed Revision 3 to RG 1.91, entitled ''Evaluations of Explosions Postulated to Occur at Nearby Facilities and on Transportation Routes Near Nuclear Power Plants,'' is temporarily identified by its task number, DG–1388 (ADAMS Accession No. ML21105A439). The staff is also issuing for public comment a draft regulatory analysis (ADAMS Accession No. ML21105A438).

The NRC published Revision 2 of RG 1.91, ''Evaluations of Explosions Postulated to Occur on Transportation Routes near Nuclear Power Plants,'' in April 2013 to provide licensees and applicants with agency-approved guidance regarding methods acceptable to the NRC staff for determining if the risk of damage at the site caused by an accidental explosion at a nearby facility or on a transportation route is sufficiently high to warrant a detailed investigation to ensure safety-related systems, structures, and components are unaffected. The current version of RG 1.91 (Revision 2) does not reflect the changes and updates with respect to the following NRC report or current methodologies as appropriate.

This proposed revision (Revision 3) reflects updates with information pertinent to addressing the recommendations of the NRC report entitled, ''Report of the U.S. Nuclear Regulatory Commission Expert Evaluation Team on Concerns Pertaining to Gas Transmission Lines Near the Indian Point Nuclear Power Plant.'' (ADAMS Accession No. ML20100F635) issued in April 2020 and current methodologies as appropriate.

III. Backfitting, Forward Fitting, and Issue Finality

DG–1388, if finalized, would not constitute backfitting as defined in section 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests'' (ADAMS Accession No. ML18093B087); would not constitute forward fitting as that term is defined and described in MD 8.4; and would not affect the issue finality of any approval issued under 10 CFR part 52, ''Licenses, Certificates, and Approvals for Nuclear Power Plants.'' As explained in DG–1388, applicants and licensees are not required to comply with the positions set forth in DG–1388.

Dated: July 27, 2021.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guidance and Programs, Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2021–16340 Filed 7–30–21; 8:45 am]

BILLING CODE 7590–01–P

SECURITIES AND EXCHANGE COMMISSION

[Investment Company Act Release No. 34345; File No. 812–15239]

Columbia ETF Trust I, et al.

July 27, 2021.

AGENCY: Securities and Exchange Commission (''Commission'').

ACTION: Notice.

Notice of an application for an order under section 6(c) of the Investment Company Act of 1940 (''Act'') for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and

rule 22c–1 under the Act, and under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act, and under Section 12(d)(1)(J) of the Act for an exemption from sections 12(d)(1)(A) and 12(d)(1)(B) of the Act.

APPLICANTS: Columbia ETF Trust I (the ''Trust''), Columbia Management Investment Advisers, LLC (the ''Adviser''), and Columbia Management Investment Distributors, Inc. (the ''Distributor'').

SUMMARY OF APPLICATION: Applicants request an order (''Order'') that permits: (a) The Funds (defined below) to issue shares (''Shares'') redeemable in large aggregations only (''creation units''); (b) secondary market transactions in Shares to occur at negotiated market prices rather than at net asset value; (c) certain Funds to pay redemption proceeds, under certain circumstances, more than seven days after the tender of Shares for redemption; and (d) certain affiliated persons of a Fund to deposit securities into, and receive securities from, the Fund in connection with the purchase and redemption of creation units. The relief in the Order would incorporate by reference terms and conditions of the same relief of a previous order granting the same relief sought by applicants, as that order may be amended from time to time (''Reference Order'').[1]

FILING DATE: The application was filed on June 16, 2021 and amended on July 1, 2021.

HEARING OR NOTIFICATION OF HEARING: An order granting the requested relief will be issued unless the Commission orders a hearing. Interested persons may request a hearing by emailing the Commission's Secretary at *Secretarys-Office@sec.gov* and serving applicants with a copy of the request by email. Hearing requests should be received by the Commission by 5:30 p.m. on August 23, 2021, and should be accompanied by proof of service on applicants, in the form of an affidavit or, for lawyers, a certificate of service. Pursuant to rule 0–5 under the Act, hearing requests should state the nature of the writer's interest, any facts bearing upon the desirability of a hearing on the matter, the reason for the request, and the issues contested. Persons who wish to be notified of a hearing may request notification by emailing the Commission's Secretary at *Secretarys-Office@sec.gov.*

ADDRESSES: Secretary, U.S. Securities and Exchange Commission, *Secretarys-Office@sec.gov.* Applicants: Joseph D'Alessandro, Columbia Management Investment Distributors, Inc., *joseph.l.dalessandro@ampf.com.*

FOR FURTHER INFORMATION CONTACT: Laura L. Solomon, Senior Counsel, at (202) 551–6915 or Lisa Reid Ragen, Branch Chief, at (202) 551–6825 (Division of Investment Management, Chief Counsel's Office).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained via the Commission's website by searching for the file number, or for an applicant using the Company name box, at *http://www.sec.gov/search/search.htm* or by calling (202) 551–8090.

Applicants

1. The Trust is a Massachusetts business trust and will consist of one or more series operating as a Fund. The Trust is registered as an open-end management investment company under the Act. Applicants seek relief with respect to Funds (as defined below), including the initial Fund (the ''Initial Fund''). The Funds will offer exchange-traded shares utilizing active management investment strategies as contemplated by the Reference Order.[2]

2. The Adviser, a Minnesota limited liability company, will be the investment adviser to the Initial Fund. Subject to approval by the Trust's board of trustees, an Adviser (as defined below) will serve as investment adviser to each Fund. The Adviser is, and any other Adviser will be, registered as an investment adviser under the Investment Advisers Act of 1940 (''Advisers Act''). An Adviser may enter into sub-advisory agreements with other investment advisers to act as sub-advisers with respect to the Funds (each a ''Sub-Adviser''). Any Sub-Adviser to a Fund will be registered under the Advisers Act.

3. The Distributor is a Delaware corporation and a broker-dealer registered under the Securities Exchange Act of 1934, as amended, and will act as the principal underwriter of Shares of the Funds. Applicants request that the requested relief apply to any distributor of Shares, whether affiliated or unaffiliated with the Adviser and/or Sub-Adviser (included in the term ''Distributor''). Any Distributor will comply with the terms and conditions of the Order.

Applicants' Requested Exemptive Relief

4. Applicants seek the requested Order under section 6(c) of the Act for an exemption from sections 2(a)(32), 5(a)(1), 22(d) and 22(e) of the Act and rule 22c–1 under the Act, under sections 6(c) and 17(b) of the Act for an exemption from sections 17(a)(1) and 17(a)(2) of the Act and under Section 12(d)(1)(J) of the Act for an exemption from Sections 12(d)(1)(A) and 12(d)(1)(B) of the Act. The requested Order would permit applicants to offer Funds that operate as contemplated by the Reference Order. Because the relief requested is the same as certain of the relief granted by the Commission under the Reference Order and because the Adviser has entered into a licensing agreement with Fidelity Management & Research Company, or an affiliate thereof, in order to offer Funds that operate as contemplated by the Reference Order,[3] the Order would incorporate by reference the terms and conditions of the same relief of the Reference Order.

5. Applicants request that the Order apply to the Initial Fund and to any other existing or future registered open-end management investment company or series thereof that: (a) Is advised by the Adviser or any entity controlling, controlled by, or under common control with the Adviser (any such entity included in the term ''Adviser''); (b) offers exchange-traded shares utilizing active management investment strategies as contemplated by the Reference Order; and (c) complies with the terms and conditions of the Order and the terms and conditions of the Reference Order that are incorporated by reference into the Order (each such company or series and each Initial Fund, a ''Fund'').[4]

6. Section 6(c) of the Act provides that the Commission may exempt any person, security or transaction, or any

[1] Fidelity Beach Street Trust, et al., Investment Company Act Rel. Nos. 33683 (Nov. 14, 2019) (notice) and 33712 (Dec. 10, 2019) (order). Applicants are not seeking relief under Section 12(d)(1)(J) of the Act for an exemption from Sections 12(d)(1)(A) and 12(d)(1)(B) of the Act (the ''Section 12(d)(1) Relief''), or relief under Sections 6(c) and 17(b) of the Act for an exemption from Sections 17(a)(1) and 17(a)(2) of the Act relating to the Section 12(d)(1) Relief, except as necessary to allow a Fund's receipt of Representative ETFs included in its Tracking Basket solely for purposes of effecting transactions in Creation Units (as these terms are defined in the Reference Order), notwithstanding the limits of Rule 12d1–4(b)(3). Accordingly, to the extent the terms and conditions of the Reference Order relate to such relief, they are not incorporated by reference herein other than with respect to such limited exception.

[2] To facilitate arbitrage, among other things, each day a Fund will publish a basket of securities and cash that, while different from the Fund's portfolio, is designed to closely track its daily performance.

[3] Certain aspects of how the Funds will operate (as described in the Reference Order) are the intellectual property of Fidelity Management & Research Company (or its affiliates).

[4] All entities that currently intend to rely on the Order are named as applicants. Any other entity that relies on the Order in the future will comply with the terms and conditions of the Order and the terms and conditions of the Reference Order that are incorporated by reference into the Order.

class of persons, securities or transactions, from any provisions of the Act, if and to the extent that such exemption is necessary or appropriate in the public interest and consistent with the protection of investors and the purposes fairly intended by the policy and provisions of the Act. Section 17(b) of the Act authorizes the Commission to exempt a proposed transaction from section 17(a) of the Act if evidence establishes that the terms of the transaction, including the consideration to be paid or received, are reasonable and fair and do not involve overreaching on the part of any person concerned, and the transaction is consistent with the policies of the registered investment company and the general purposes of the Act. Section 12(d)(1)(J) of the Act provides that the Commission may exempt any person, security, or transaction, or any class or classes of persons, securities or transactions, from any provision of section 12(d)(1) if the exemption is consistent with the public interest and the protection of investors. Applicants submit that for the reasons stated in the Reference Order the requested relief meets the exemptive standards under sections 6(c), 17(b) and 12(d)(1)(J) of the Act.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–16373 Filed 7–30–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–349, OMB Control No. 3235–0395]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 15g–6

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 15g–6—Account Statements for Penny Stock Customers—(17 CFR 240.15g–6) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 15g–6 requires brokers and dealers that sell penny stocks to provide their customers monthly account statements containing information with regard to the penny stocks held in customer accounts. The purpose of the rule is to increase the level of disclosure to investors concerning penny stocks generally and specific penny stock transactions.

The Commission estimates that approximately 178 broker-dealers will spend an average of approximately 78 hours annually to comply with this rule. Thus, the total compliance burden is approximately 13,884 burden-hours per year.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–16409 Filed 7–30–21; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–330, OMB Control No. 3235–0372]

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of FOIA Services, Washington, DC 20549–0213

Extension:
Rule 15c2–12

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 15c2–12—Municipal Securities Disclosure (17 CFR 240.15c2–12) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Paragraph (b) of Rule 15c2–12 requires underwriters of municipal securities: (1) To obtain and review an official statement ''deemed final'' by an issuer of the securities, except for the omission of specified information prior to making a bid, purchase, offer, or sale of municipal securities; (2) in non-competitively bid offerings, to send, upon request, a copy of the most recent preliminary official statement (if one exists) to potential customers; (3) to contract with the issuer to receive, within a specified time, sufficient copies of the final official statement to comply with Rule 15c2–12's delivery requirement and the rules of the Municipal Securities Rulemaking Board (''MSRB''); (4) to send, upon request, a copy of the final official statement to potential customers for a specified period of time; and (5) before purchasing or selling municipal securities in connection with an offering, to reasonably determine that the issuer or the obligated person has undertaken, in a written agreement or contract, for the benefit of holders of such municipal securities, to provide certain information on a continuing basis to the MSRB in an electronic format as prescribed by the MSRB. The information to be provided consists of: (1) Certain annual financial and operating information and audited financial statements (''annual filings''); (2) notices of the occurrence of any of 16 specific events (''event notices''); and (3) notices of the failure of an issuer or

obligated person to make a submission required by a continuing disclosure agreement (''failure to file notices'').

Rule 15c2–12 is intended to enhance disclosure, and thereby reduce fraud, in the municipal securities market by establishing standards for obtaining, reviewing and disseminating information about municipal securities by their underwriters.

Municipal offerings of less than $1 million are exempt from the rule, as are offerings of municipal securities issued in large denominations that are sold to no more than 35 sophisticated investors or have short-term maturities.

It is estimated that approximately 28,000 issuers, 250 broker-dealers and the MSRB will spend a total of 797,681 hours per year complying with Rule 15c2–12.[1] Based on data from the MSRB through December 2020, issuers annually submit approximately 61,964 annual filings to the MSRB. Commission staff estimates that an issuer will require approximately seven hours to prepare and submit annual filings to the MSRB. Therefore, the total annual burden on issuers to prepare and submit 61,964 annual filings to the MSRB is estimated to be 433,748 hours. Based on data from the MSRB through December 2020, issuers annually submit approximately 54,121 event notices to the MSRB. Commission staff estimates that an issuer will require approximately four hours to prepare and submit event notices to the MSRB. Therefore, the total annual burden on issuers to prepare and submit 54,121 event notices to the MSRB is estimated to be 216,484 hours. Based on data from the MSRB through December 2020, issuers annually submit approximately 3,597 failure to file notices to the MSRB. Commission staff estimates that an issuer will require approximately two hours to prepare and submit failure to file notices to the MSRB. Therefore, the total annual burden on issuers to prepare and submit 3,597 failure to file notices to the MSRB is estimated to be 7,194 hours. Commission staff estimates that the total annual burden on broker-dealers to comply with Rule 15c2–12 is 115,255 hours. Finally, Commission staff estimates that the MSRB will incur an annual burden of 25,000 hours to collect, index, store, retrieve and make available the pertinent documents under Rule 15c2–12.

The Commission estimates that up to 65% of issuers may use designated agents to submit some or all of their continuing disclosure documents to the MSRB. The Commission estimates that the average total annual cost that may be incurred by issuers that use the services of a designated agent will be $15,470,000.[2] Further, the Commission estimates that issuers will retain outside counsel to assist with filing approximately 1,100 event notices. The Commission estimates the average total annual cost incurred by issuers to retain outside counsel to assist in the evaluation and preparation of certain event notices will be $1,760,000.[3] Thus, the total estimated cost to issuers to comply with the rule is $17,230,000.[4] The Commission estimates that the MSRB will incur total annual costs of $670,000 to operate the continuing disclosure service for the MSRB's Electronic Municipal Market Access (''EMMA'') system.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number. Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–16404 Filed 7–30–21; 8:45 am]

BILLING CODE 8011–01–P

[1] 54,121 (annual number of event notices) × 4 (average estimate of hours needed to prepare and submit each) + 61,964 (annual number of annual filings) × 7 (average estimate of hours needed to prepare and submit each) + 3,597 (annual number of failure to file notices) × 2 (average estimate of hours needed to prepare and submit each) = 657,426 hours. 657,426 hours (estimated total annual burden on issuers) + 25,000 (estimated total annual MSRB burden) + 115,255 (estimated total annual burden on broker-dealers) = 797,681 hours.

[2] 28,000 (number of issuers) × .65 (percentage of issuers that may use designated agents) × $850 (estimated average annual cost for issuer's use of designated agent to submit filings to the Rule) = $15,470,000.

[3] 1,100 (estimate of number of event notices requiring outside counsel) × 4 (estimated number of hours for outside attorney to assist in the preparation of such event notice) × $400 (hourly wage for an outside attorney) = $1,760,000. The Commission recognizes that the costs of retaining outside professionals may vary depending on the nature of the professional services, but for purposes of this PRA analysis we estimate that costs of outside counsel would be an average of $400 per hour.

[4] $15,470,000 (estimated total cost for issuer's use of designated agent to submit filings) + $1,760,000 (estimated total cost for issuer to employ outside counsel in the examination, preparation, and filing of certain event notices) = $17,230,000.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–098, OMB Control No. 3235–0081]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 12d2–1

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 12d2–1(17 CFR 240.12d2–1) under the Securities Exchange Act of 1934 (15 U.S.C. 78b *et seq.*) (''Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

On February 12, 1935, the Commission adopted Rule 12d2–1 [1]('' Suspension of Trading'') to establish the procedures by which a national securities exchange may suspend from trading a security that is listed and registered on the exchange under Section 12(d) of the Act.[2] Under Rule 12d2–1, an exchange is permitted to suspend from trading a listed security in accordance with its rules, and must promptly notify the Commission of any such suspension, along with the effective date and the reasons for the suspension.

Any such suspension may be continued until such time as the Commission may determine that the suspension is designed to evade the

[1] *See* Securities Exchange Act Release No. 98 (February 12, 1935).

[2] *See* Securities Exchange Act Release No. 7011 (February 5, 1963), 28 FR 1506 (February 16, 1963).

provisions of Section 12(d) of the Act and Rule 12d2–2 thereunder.[3] During the continuance of such suspension under Rule 12d2–1, the exchange is required to notify the Commission promptly of any change in the reasons for the suspension. Upon the restoration to trading of any security suspended under Rule 12d2–1, the exchange must notify the Commission promptly of the effective date of such restoration.

The trading suspension notices serve a number of purposes. First, they inform the Commission that an exchange has suspended from trading a listed security or reintroduced trading in a previously suspended security. They also provide the Commission with information necessary for it to determine that the suspension has been accomplished in accordance with the rules of the exchange, and to verify that the exchange has not evaded the requirements of Section 12(d) of the Act and Rule 12d2–2 thereunder by improperly employing a trading suspension. Without Rule 12d2–1, the Commission would be unable to fully implement these statutory responsibilities.

There are 24 national securities exchanges[4] that are subject to Rule 12d2–1. The burden of complying with Rule 12d2–1 is not evenly distributed among the exchanges, however, since there are many more securities listed on the New York Stock Exchange, Inc., the NASDAQ Stock Market, and NYSE American LLC than on the other exchanges.[5] There are approximately 878 responses[6] under Rule 12d2–1 for the purpose of suspension of trading from the national securities exchanges each year, and the resultant aggregate annual reporting hour burden would be, assuming on average one-half reporting hour per response, 439 annual burden hours for all exchanges. The related internal compliance costs associated with these burden hours are $98,354 per year.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will 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 collected; and (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–16410 Filed 7–30–21; 8:45 am]

BILLING CODE 8011–01–P

[3] Rule 12d2–2 prescribes the circumstances under which a security may be delisted from an exchange and withdrawn from registration under Section 12(b) of the Act, and provides the procedures for taking such action.

[4] The Exchanges are BOX Exchange LLC, Cboe BYX Exchange, Inc., Cboe BZX Exchange, Inc., Cboe C2 Exchange, Inc., Cboe EDGA Exchange, Inc., Cboe EDGX Exchange, Inc., Cboe Exchange, Inc., Investors Exchange LLC, Long Term Stock Exchange, Inc., MEMX, LLC, Miami International Securities Exchange, MIAX Emerald, LLC, MIAX PEARL, LLC, Nasdaq BX, Inc., Nasdaq GEMX, LLC, Nasdaq ISE, LLC, Nasdaq MRX, LLC, Nasdaq PHLX LLC, The Nasdaq Stock Market, New York Stock Exchange LLC, NYSE Arca, Inc., NYSE Chicago, Inc., NYSE American LLC, NYSE National, Inc.

[5] In fact, some exchanges do not file any trading suspension reports in a given year.

[6] The 878 figure was calculated by averaging the numbers for compliance in 2019 and 2020, which are 822 and 933, respectively.

SECURITIES AND EXCHANGE COMMISSION

[SEC File No. 270–348, OMB Control No. 3235–0394]

Proposed Collection; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE, Washington, DC 20549–2736

Extension:
Rule 15g–5

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (''PRA'') (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 15g–5—Disclosure of Compensation to Associated Persons in Connection with Penny Stock Transactions—(17 CFR 240.15g–5) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

Rule 15g–5 requires brokers and dealers to disclose to customers the amount of compensation to be received by their sales agents in connection with penny stock transactions. The purpose of the rule is to increase the level of disclosure to investors concerning penny stocks generally and specific penny stock transactions.

The Commission estimates that approximately 178 broker-dealers will spend an average of approximately 87 hours annually to comply with the rule. Thus, the total time burden is approximately 15,486 hours per year.

Written comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's estimates of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (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. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

Please direct your written comments to: David Bottom, Director/Chief Information Officer, Securities and Exchange Commission, c/o Cynthia Roscoe, 100 F Street NE, Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: July 28, 2021.

J. Matthew DeLesDernier,

Assistant Secretary.

[FR Doc. 2021–16403 Filed 7–30–21; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 11475]

60-Day Notice of Proposed Information Collection: Six Directorate of Defense Trade Controls (DDTC) Information Collections

ACTION: Notice of request for public comments.

SUMMARY: The Department of State is seeking Office of Management and Budget (OMB) approval for the information collections described below. In accordance with the Paperwork Reduction Act of 1995, we are requesting comments on these collections from all interested individuals and organizations. The purpose of this notice is to allow 60 days for public comment preceding submission of the collections to OMB.

DATES: The Department will accept comments from the public up to October 1, 2021.

ADDRESSES: You may submit comments by any of the following methods:

- *Web:* Persons with access to the internet may comment on this notice by going to *www.Regulations.gov.* You can search for the document by entering ''Docket Number: DOS–2021–0018'' in the Search field. Then click the ''Comment Now'' button and complete the comment form.
- *Email: DDTCPublicComments@state.gov.*
- *Regular Mail:* Send written comments to: Andrea Battista, SA–1, 12th Floor, Directorate of Defense Trade Controls, Bureau of Political Military Affairs, U.S. Department of State, Washington, DC 20522–0112.

You must include the DS form number (if applicable), information collection title, and the OMB control number in any correspondence.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Andrea Battista, SA–1, 12th Floor, Directorate of Defense Trade Controls, Bureau of Political Military Affairs, U.S. Department of State, Washington, DC 20522–0112, via phone at (202) 663–3136, or via email at *battistaal@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data.
- *OMB Control Number:* 1405–0003.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–5.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.
- *Estimated Number of Respondents:* 1,668.
- *Estimated Number of Responses:* 19,210.
- *Average Time per Response:* 1 hour.
- *Total Estimated Burden Time:* 19,210 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required to Obtain or Retain a Benefit.

- *Title of Information Collection:* Application/License for Temporary Import of Unclassified Defense Articles.
- *OMB Control Number:* 1405–0013.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–61.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.
- *Estimated Number of Respondents:* 141.
- *Estimated Number of Responses:* 578.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 289 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required in Order to Obtain or Retain Benefits.

- *Title of Information Collection:* Application/License for Permanent/Temporary Export or Temporary Import of Classified Defense Articles and Related Classified Technical Data.
- *OMB Control Number:* 1405–0022.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–85.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.
- *Estimated Number of Respondents:* 64.
- *Estimated Number of Responses:* 277.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 138.5 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required in Order to Obtain or Retain Benefits.

- *Title of Information Collection:* Application/License for Temporary Export of Unclassified Defense Articles.
- *OMB Control Number:* 1405–0023.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–73.
- *Respondents:* Business and Nonprofit Organizations.
- *Estimated Number of Respondents:* 339.
- *Estimated Number of Responses:* 2,196.
- *Average Time per Response:* 1 hour.
- *Total Estimated Burden Time:* 2,196 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required in Order to Obtain or Retain Benefits.

- *Title of Information Collection:* Application for Amendment to License for Export or Import of Classified or Unclassified Defense Articles and Related Classified Technical Data.
- *OMB Control Number:* 1405–0092.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–6; DSP–62; DSP–74.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.
- *Estimated Number of Respondents:* 440.
- *Estimated Number of Responses:* 1,742.
- *Average Time per Response:* 30 minutes.
- *Total Estimated Burden Time:* 871 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required in Order to Obtain or Retain Benefits.

- *Title of Information Collection:* Nontransfer and Use Certificate.
- *OMB Control Number:* 1405–0021.
- *Type of Request:* Extension of Currently Approved Collection.
- *Originating Office:* Bureau of Political-Military Affairs, Directorate of Defense Trade Controls, PM/DDTC.
- *Form Number:* DSP–83.
- *Respondents:* Business, Nonprofit Organizations, and Individuals.
- *Estimated Number of Respondents:* 675.
- *Estimated Number of Responses:* 675.
- *Average Time per Response:* 1 hour.
- *Total Estimated Burden Time:* 675 hours.
- *Frequency:* On Occasion.
- *Obligation to Respond:* Required in Order to Obtain or Retain Benefits.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.

• Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of Proposed Collections

The export, temporary import, and brokering of defense articles, including technical data, and defense services are authorized by the Department of State, Directorate of Defense Trade Controls (DDTC) in accordance with the International Traffic in Arms Regulations (''ITAR,'' 22 CFR parts 120–130) and section 38 of the Arms Export Control Act. Those who manufacture, broker, export, or temporarily import defense articles, including technical data, or defense services must register with the Department of State and obtain a decision from the Department as to whether it is in the interests of U.S. foreign policy and national security to approve covered transactions. Also, registered brokers must submit annual reports regarding all brokering activity that was transacted, and registered manufacturers and exporter must maintain records of defense trade activities for five years.

• *1405–0003, Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data:* In accordance with part 123 of the ITAR, any person who intends to permanently export unclassified defense articles or unclassified technical data must obtain authorization from DDTC prior to export. ''Application/License for Permanent Export of Unclassified Defense Articles and Related Unclassified Technical Data'' (Form DSP–5) is the licensing vehicle typically used to obtain permission for the permanent export of unclassified defense articles, including unclassified technical data, enumerated on the USML. This form is an application that, when completed and approved by PM/DDTC, Department of State, constitutes the official record and authorization for the permanent commercial export of unclassified U.S. Munitions List articles, pursuant to the Arms Export Control Act and the International Traffic in Arms Regulations.

• *1405–0013, Application/License for Temporary Import of Unclassified Defense Articles:* In accordance with part 123 of the ITAR, any person who intends to temporarily import unclassified defense articles must obtain DDTC authorization prior to import. ''Application/License for Temporary Import of Unclassified Defense Articles'' (Form DSP–61) is the licensing vehicle typically used to obtain permission for the temporary import of unclassified defense articles covered by USML. This form is an application that, when completed and approved by PM/DDTC, Department of State, constitutes the official record and authorization for the temporary commercial import of unclassified U.S. Munitions List articles, pursuant to the Arms Export Control Act and the International Traffic in Arms Regulations.

• *1405–0022, Application/License for Permanent/Temporary Export or Temporary Import of Classified Defense Articles and Related Classified Technical Data:* In accordance with part 123 of the ITAR, any person who intends to permanently export, temporarily export, or temporarily import classified defense articles, including classified technical data must first obtain DDTC authorization. ''Application/License for Permanent/Temporary Export or Temporary Import of Classified Defense Articles and Related Classified Technical Data'' (Form DSP–85) is used to obtain permission for the permanent export, temporary export, or temporary import of classified defense articles, including classified technical data, covered by the USML. This form is an application that, when completed and approved by PM/DDTC, Department of State, constitutes the official record and authorization for all classified commercial defense trade transactions, pursuant to the Arms Export Control Act and the International Traffic in Arms Regulations.

• *1405–0023, Application/License for Temporary Export of Unclassified Defense Articles:* In accordance with part 123 of the ITAR, any person who intends to temporarily export unclassified defense articles must DDTC authorization prior to export. ''Application/License for Temporary Export of Unclassified Defense Articles'' (Form DSP–73) is the licensing vehicle typically used to obtain permission for the temporary export of unclassified defense articles covered by the USML. This form is an application that, when completed and approved by PM/DDTC, Department of State, constitutes the official record and authorization for the temporary commercial export of unclassified U.S. Munitions List articles, pursuant to the Arms Export Control Act and the International Traffic in Arms Regulations.

• *1405–0092, Application for Amendment to License for Export or Import of Classified or Unclassified Defense Articles and Related Classified Technical Data:* In accordance with part 123 of the ITAR, any person who intends to permanently export, temporarily import, or temporarily export unclassified or classified defense articles or related technical data must obtain DDTC authorization. ''Application for Amendment to License for Export or Import of Classified or Unclassified Defense Articles and Related Classified Technical Data'' is used to obtain permission for certain changes to previously approved licenses. This form is an application that, when completed and approved by PM/DDTC, Department of State, constitutes the official record and authorization for all requests to amend existing defense trade authorizations made pursuant to the Arms Export Control Act and the International Traffic in Arms Regulations.

• *1405–0021, Nontransfer and Use Certificate:* Pursuant to § 123.10 of the ITAR, a completed ''Nontransfer and Use Certificate'' (Form DSP–83) must accompany an export license application to export significant military equipment and classified articles and technical data. Pursuant to § 124.10 of the ITAR, a completed ''Nontransfer and Use Certificate'' must be submitted with any request for a manufacturing license agreement or technical assistance agreement that relates to significant military equipment or classified defense articles and technical data. The foreign consignee (if applicable), foreign end-user, and applicant execute this form. By signing the certificate the foreign end-user certifies that they will not, except as specifically authorized by prior written approval of the Department of State, re-export, resell or otherwise dispose of the defense articles enumerated in the application (1) outside the foreign country named as the country of ultimate destination; or (2) to any other person. With respect to agreements that involve classified articles or classified technical data, an authorized representative of the foreign government must also sign the form.

Methodology

This information collection may be sent to the Directorate of Defense Trade Controls via the following methods: Electronically or mail.

Neal F. Kringel,

Director of Management, Bureau of Political-Military Affairs, U.S. Department of State.

[FR Doc. 2021–16357 Filed 7–30–21; 8:45 am]

BILLING CODE 4710–25–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 1310 (Sub-No. 1X)]

Northwestern Pacific Railroad Company—Discontinuance of Service Exemption—in Mendocino County, Cal.

Northwestern Pacific Railroad Company (NWPCO) has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments and Discontinuances of Service* to discontinue service over an approximately 53.5-mile rail line extending between approximately milepost NWP 142.5 near Outlet Station and approximately milepost NWP 89 near the Sonoma-Mendocino County, Cal., border in Mendocino County, Cal. (the Line).[1] The Line traverses U.S. Postal Service Zip Codes 95490, 95470, 95482, 95449, and 95425.

NWPCO has certified that: (1) It has handled no local traffic over the Line for at least two years;[2] (2) it has not handled overhead traffic on the Line and there is no potential overhead traffic that would need to be rerouted; (3) no formal complaint filed by a user of rail service on the Line (or a state or local government entity acting on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board or any U.S. District Court or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.12 (newspaper publication) and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

The verified notice states that the Line ''comprises the entirety of NWPCO's remaining common carrier operating authority.''[3] Where, as here, the carrier is discontinuing service over its entire system, the Board does not normally impose labor protection under 49 U.S.C. 10502(g), unless the evidence indicates the existence of: (1) a corporate affiliate that will continue substantially similar rail operations; or (2) a corporate parent that will realize substantial financial benefits over and above relief from the burden of deficit operations by its subsidiary railroad. *See Honey Creek R.R.—Aban. Exemption—in Henry Cnty., Ind.,* AB 865X (STB served Aug. 20, 2004); *Northampton & Bath R.R.—Aban. near Northampton & Bath Junction in Northampton Cnty., Pa.,* 354 I.C.C. 784 (1978); *Wellsville, Addison & Galeton R.R.—Aban. of Entire Line in Potter & Tioga Cntys., Pa.,* 354 I.C.C. 744 (1978). According to NWPCO, it does not have a corporate affiliate that has similar rail operations, and there is no corporate parent that will benefit from the proposed discontinuance. Therefore, employee protection conditions will not be imposed.

Provided no formal expression of intent to file an offer of financial assistance (OFA)[4] to subsidize continued rail service has been received, this exemption will be effective on September 1, 2021, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues and formal expressions of intent to file an OFA to subsidize continued rail service under 49 CFR 1152.27(c)(2)[5] must be filed by August 12, 2021.[6] Petitions for reconsideration must be filed by August 23, 2021.

All pleadings, referring to Docket No. AB 1310 (Sub-No. 1X) should be filed with the Surface Transportation Board via e-filing on the Board's website. In addition, a copy of each pleading filed with the Board must be served on NWPCO's representative, Justin J. Marks, Clark Hill PLC, 1001 Pennsylvania Avenue NW, Suite 1300 South, Washington, DC 20004.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Board decisions and notices are available at *www.stb.gov.*

Decided: July 27, 2021.

By the Board, Scott M. Zimmerman, Acting Director, Office of Proceedings.

Regena Smith-Bernard,

Clearance Clerk.

[FR Doc. 2021–16372 Filed 7–30–21; 8:45 am]

BILLING CODE 4915–01–P

[1] According to NWPCO, it holds common carrier authority to operate over the Line pursuant to a lease agreement with the North Coast Railroad Authority (NCRA). *See Nw. Pac. R.R.—Change in Operators Exemption—N. Coast R.R. Auth.,* FD 35073 (STB served Aug. 30, 2007). NCRA has filed a verified notice of exemption to abandon 175.84 miles of rail line, including an approximately three-mile segment of the Line between milepost 139.5 and milepost 142.5. *See* NCRA, Notice of Exemption 1, *N. Coast R.R.—Aban. Exemption—in Mendocino, Trinity & Humboldt Cntys., Cal.,* AB 1305X.

[2] NWPCO states that it has never offered service on the Line due to Emergency Order 21 issued by the Federal Railroad Administration prohibiting railroad operations since 1998.

[3] NWPCO states that it previously discontinued operations over a connecting rail line segment between milepost NWP 89 and milepost SP 63.4. *See Nw. Pac. R.R.—Discontinuance of Serv. Exemption—in Marin, Napa, & Sonoma Cntys., Cal.,* AB 1310X (STB served June 11, 2021).

[4] Persons interested in submitting an OFA to subsidize continued rail service must first file a formal expression of intent to file an offer, indicating the intent to file an OFA for subsidy and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[5] The filing fee for OFAs can be found at 49 CFR 1002.2(f)(25).

[6] Because this is a discontinuance proceeding and not an abandonment, interim trail use/rail banking and public use conditions are not appropriate. Because there will be an environmental review during abandonment, this discontinuance does not require environmental review.

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

Notice of Final Federal Agency Actions on Proposed Highway in Washington

AGENCY: Federal Highway Administration (FHWA), Department of Transportation (DOT).

ACTION: Notice of limitation on claims for judicial review of actions by FHWA.

SUMMARY: This notice announces actions taken by the FHWA that are final. The actions relate to National Environmental Policy Act (NEPA) approvals for a proposed highway project, the I–405, SR 522 Vicinity to SR 527 Express Toll Lanes Improvement Project between Mileposts 21.79 and 27.06, located mostly in Bothell, Washington in the Counties of King and Snohomish, State of Washington.

DATES: By this notice, the FHWA is advising the public of final agency actions subject to 23 U.S.C. 139(*l*)(1). A claim seeking judicial review of the Federal agency actions on the highway project will be barred unless the claim is filed on or before December 30, 2021. If the Federal law that authorizes judicial review of a claim provides a time period of less than 150 days for filing such claim, then that shorter time period still applies.

FOR FURTHER INFORMATION CONTACT: For FHWA, Lindsey Handel, Area Engineer, Federal Highway Administration, 711 S Capitol Way, Suite 501, Olympia, WA 98501–1284, 360–753–9480, *lindsey.handel@dot.gov*; or Robert Woeck, I–405/SR 167 Megaprogram Deputy Program Administrator, Washington State Department of Transportation, 600 108th Avenue NE, Suite 405, Bellevue, Washington 98004, 425–456–8585, *woeckro@wsdot.wa.gov*.

SUPPLEMENTARY INFORMATION: Notice is hereby given that FHWA has taken final agency action(s) subject to 23 U.S.C. 139(l)(1) by issuing National Environmental Policy Act approvals for the following highway project in the State of Washington: The I–405, SR 522 Vicinity to SR 527 Express Toll Lanes Improvement Project (Project) proposes to make roadway, structural, trail, and transit infrastructure improvements to I–405 from milepost (MP) 21.79 to MP 27.06, located mostly in Bothell,

Washington. The Project proposes to create a dual express toll lane (ETL) system by restriping existing lanes from MP 21.79 to MP 22.30 and widening I–405 to add one ETL in each direction between MP 22.30 and MP 26.30. At the SR 522 interchange, the Project would construct direct access ramps to and from the ETL, inline transit stations in the I–405 median, and three new signalized intersections on SR 522, which would change where the freeway portion of SR 522 begins and ends. Just south of the SR 527 interchange at 17th Avenue SE, the Project would construct direct access ramps to and from the ETL and inline transit stations in the I–405 median. The Project would reconstruct new bridges over the Sammamish River, build three new noise walls, construct bicycle and pedestrian facilities, reconfigure local streets, correct five fish barriers, and make stormwater improvements.

The actions by the Federal agencies, and the laws under which such actions were taken, are described in the I–405, SR 522 Vicinity to SR 527 Express Toll Lanes Improvement Project Environmental Assessment (EA) issued on July 2, 2020, Finding of No Significant Impact (FONSI) for the project published on July 29, 2021 and in other documents in the project records. The EA, FONSI, and other project records are available from FHWA and WSDOT at the addresses provided in the ''For Further Information Contact'' section of this notice and can be found at: *http://www.wsdot.wa.gov/Projects/i405/sr-522-sr-527/environmental-review/.*

This notice applies to all Federal agency decisions that are final as of the issuance date of this notice and all laws under which such actions were taken, including but not limited to:

1. General: National Environmental Policy Act (NEPA) (42 U.S.C. 4321–4351); Federal-Aid Highway Act (23 U.S.C. 109 and 23 U.S.C. 128).

2. Air: Clean Air Act (42 U.S.C. 7401–7671q).

3. Land: Section 4(f) of the Department of Transportation Act of 1966 (49 U.S.C. 303; 23 U.S.C. 138); Landscaping and Scenic Enhancement (Wildflowers) (23 U.S.C. 319).

4. Wildlife: Endangered Species Act (16 U.S.C. 1531–1544 and Section 1536); Marine Mammal Protection Act (16 U.S.C. 1361–1423h); Fish and Wildlife Coordination Act (16 U.S.C. 661–667d); Migratory Bird Treaty Act (16 U.S.C. 703–712).

5. Historic and Cultural Resources: Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470f); Archeological Resources Protection Act of 1977 (16 U.S.C. 470aa–470mm); Archeological and Historic Preservation Act (16 U.S.C. 469–469c); Native American Grave Protection and Repatriation Act (NAGPRA) (25 U.S.C. 3001–3013).

6. Social and Economic: American Indian Religious Freedom Act (42 U.S.C. 1996); Farmland Protection Policy Act (FPPA) (7 U.S.C. 4201–4209).

7. Wetlands and Water Resources: Clean Water Act (Section 404, Section 401, Section 319) (33 U.S.C. 1251–1387); Land and Water Conservation Fund (LWCF) (16 U.S.C. 4601–4604); Safe Drinking Water Act (SDWA) (42 U.S.C. 300f–300j–26)); Rivers and Harbors Act of 1899 (33 U.S.C. 401–406); Wild and Scenic Rivers Act (16 U.S.C. 1271–1287); Emergency Wetlands Resources Act, (16 U.S.C. 3901, 3921); Wetlands Mitigation (23 U.S.C. 119(g) and 133(b)(14)); Flood Disaster Protection Act, 42 U.S.C. 4012a, 4106).

8. Executive Orders: E.O. 11990 Protection of Wetlands; E.O. 11988 Floodplain Management; E.O. 12898, Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations; E.O. 11593 Protection and Enhancement of Cultural Resources; E.O. 13007 Indian Sacred Sites; E.O. 13287 Preserve America; E.O. 13175 Consultation and Coordination with Indian Tribal Governments; E.O. 11514 Protection and Enhancement of Environmental Quality; E.O. 13112 Invasive Species.

(Catalog of Federal Domestic Assistance Program Number 20.205, Highway Planning and Construction. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities apply to this program.)

Authority: 23 U.S.C. 139(*l*)(1).

Issued on: July 26, 2021.

Melinda Roberson,

Acting Division Administrator, Federal Highway Administration, Olympia, Washington.

[FR Doc. 2021–16320 Filed 7–30–21; 8:45 am]

BILLING CODE 4910–RY–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2020–0031]

Petition for Approval Extension: Union Pacific Railroad

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of petition for an extension of approval of track inspection test program.

SUMMARY: This document provides the public notice that on July 21, 2021, Union Pacific Railroad (UP) petitioned the Federal Railroad Administration (FRA) to extend an existing temporary suspension of some visual track inspections to allow for the continuation of a previously approved Test Program designed to test track inspection technologies (*i.e.,* an autonomous track geometry measurement system) and new operational approaches to track inspections (*i.e.,* combinations of autonomous inspection and traditional visual inspections).

FOR FURTHER INFORMATION CONTACT: Yu-Jiang Zhang, Staff Director, Track and Structures Division, at (202) 493–6460 or *yujiang.zhang@dot.gov;* or Aaron Moore, Attorney, Office of the Chief Counsel, at (202) 493–7009 or *aaron.moore@dot.gov.*

SUPPLEMENTARY INFORMATION: On April 28, 2020, FRA conditionally approved the Test Program and UP's petition under 49 CFR 211.51 to suspend § 213.233(c) as applied to operations under the Test Program. Accordingly, a copy of the Test Program, FRA's conditional approval of the Test Program, and a previously published **Federal Register** notice explaining FRA's rationale for approving the Test Program and related suspension are available for review in the docket.[1]

As approved, the Test Program includes two separate phases over 12 months, as outlined in Exhibit C of the Program.[2] UP began the Test Program on June 15, 2020. Accordingly, the Test Program expired on June 15, 2021. UP is requesting to renew and extend the Test Program for one year, until June 15, 2022, to complete the Program.

A copy of the petition, as well as any written communications concerning the petition, if any, are available for review online at *www.regulations.gov.*

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments.

All communications concerning these proceedings should identify the appropriate docket number and may be

[1] *https://www.regulations.gov/document/FRA-2020-0031-0001* (Test Program); *https://www.regulations.gov/document/FRA-2020-0031-0002* (FRA's approval decision); *https://www.regulations.gov/document/FRA-2020-0031-0004* (FRA's published notice of approval).

[2] *See https://www.regulations.gov/document/FRA-2020-0031-0001.*

submitted by any of the following methods:

• *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.

Communications received by September 7, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety Chief Safety Officer.

[FR Doc. 2021–16441 Filed 7–30–21; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2021–0006–N–9]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of information collection; request for comment.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA), this notice announces that FRA is forwarding the Information Collection Request (ICR) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICR describes the information collection and its expected burden. On May 17, 2021, FRA published a notice providing a 60-day period for public comment on the ICR.

DATES: Interested persons are invited to submit comments on or before September 1, 2021.

ADDRESSES: Written comments and recommendations for the proposed ICR should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular ICR by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: Ms. Kim Toone, Information Collection Clearance Officer, at email: *Kim.Toone@dot.gov* or telephone: (202) 493–6132.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520, and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.8 through 1320.12. On May 17, 2021, FRA published a 60-day notice in the **Federal Register** soliciting comment on the ICR for which it is now seeking OMB approval. *See* 86 FR 26771. FRA received no comments in response to this 60-day notice.

Before OMB decides whether to approve the proposed collection of information, it must provide 30 days for public comment. Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. 44 U.S.C. 3507(b)–(c); 5 CFR 1320.10(b); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure having their full effect.

Comments are invited on the following ICR regarding: (1) Whether the information collection activities are necessary for FRA to properly execute its functions, including whether the information will have practical utility; (2) the accuracy of FRA's estimates of the burden of the information collection activities, including the validity of the methodology and assumptions used to determine the estimates; (3) ways for FRA to enhance the quality, utility, and clarity of the information being collected; and (4) ways to minimize the burden of information collection activities on the public, including the use of automated collection techniques or other forms of information technology.

The summary below describes the ICR that FRA will submit for OMB clearance as the PRA requires:

Title: Grants Management Requirements for Federal Railroad Administration. Grants Awards and Cooperative Agreements.

OMB Control Number: 2130–0615.

Abstract: This ICR is a revision of a currently approved collection, Grant Management Requirements for Federal Railroad Administration. Specifically, FRA is revising FRA Form 217 (Categorical Exclusion Worksheet) with this submission. All other forms associated with this collection, which OMB re-approved on January 7, 2021, remain unchanged. The forms for which FRA seeks renewal of its currently approved collection are listed below.

Form(s): All FRA forms (Fs) are located at FRA's public website; all Standard Forms (SFs) are located at *Grants.gov.* The FRA forms are: 30 (FRA Assurance and Certifications Regarding Lobbying; Debarment, Suspension and Other Responsibility Matters and Drug-Free Workplace Requirements), 31 (Grant Adjustment Require Form), 32 (Service Outcome Agreement Annual Reporting), 33 (Final Performance Report), 34 (Quarterly Progress Report), 35 (Application Form), 217 (Categorical Exclusion Worksheet), 229 (NIST Manufacturing Extension Partnership Supplier Scouting—FRA Item Opportunity Synopsis), 251 (Applicant Financial Capability Questionnaire), and 252 (Payment Summary Spreadsheet). The SFs are: 270 (Request for Advance or Reimbursement), 424 (Application for Federal Assistance), 424A (Budget Information for Non-Construction Programs), 424B (Assurance for Non-Construction Programs), 424C (Budget Information for Construction Programs), 424D (Assurances for Construction Programs), 425 (Federal Financial Report), and LLL (Disclosure of Lobbying Activities).

Type of Request: Revision of a currently approved collection.

Affected Public: Generally includes States and local governments and railroads.

Frequency of Submission: Varied; on occasion/monthly.

Total Estimated Annual Responses: 6,570.

Total Estimated Annual Burden: 20,184.50 hours.

Total Estimated Annual Burden Hour Dollar Cost Equivalent: $827,362.66.

Under 44 U.S.C. 3507(a) and 5 CFR 1320.5(b) and 1320.8(b)(3)(vi), FRA informs all interested parties that a respondent is not required to respond to, conduct, or sponsor a collection of information unless it displays a currently valid OMB control number.

Authority: 44 U.S.C. 3501–3520.

Brett A. Jortland,

Acting Chief Counsel.

[FR Doc. 2021–16429 Filed 7–30–21; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket No. FRA–2019–0099]

Petition for Approval Extension: Norfolk Southern Railway Company

AGENCY: Federal Railroad Administration (FRA), Department of Transportation (DOT).

ACTION: Notice of petition for extension of approval of track inspection test program.

SUMMARY: This document provides the public notice that on July 19, 2021, Norfolk Southern Railway Company (NS) petitioned the Federal Railroad Administration (FRA) to extend an existing temporary suspension of some visual track inspections to allow for a continuation of a previously approved Test Program designed to test track inspection technologies (*i.e.,* an autonomous track geometry measurement system) and new operational approaches to track inspections (*i.e.,* combinations of autonomous inspection and traditional visual inspections).

FOR FURTHER INFORMATION CONTACT: Yu-Jiang Zhang, Staff Director, Track and Structures Division, at (202) 493–6460 or *yujiang.zhang@dot.gov;* or Aaron Moore, Attorney, Office of the Chief Counsel, at (202) 493–7009 or *aaron.moore@dot.gov.*

SUPPLEMENTARY INFORMATION: On January 27, 2020, FRA conditionally approved the Test Program and NS's petition under 49 CFR 211.51 to suspend §§ 213.233(b)(3) and 213.233(c) as applied to operations under the Test Program. A copy of the Test Program, FRA's conditional approval of the Test Program, and a previously published **Federal Register** notice explaining FRA's rationale for approving the Test Program and related suspension are available for review in the docket.[1]

As approved, the Test Program included three separate phases over 12 months as outlined in Exhibit C of the Program.[2] Accordingly, NS began the Test Program on March 16, 2020. However, FRA has approved extending the Test Program twice as requested by NS. Thus, the Test Program is currently set to expire on September 31, 2021.

On March 22, 2021, NS submitted a waiver petition[3] to permit a reduced frequency of manual track inspections where an automated track geometry measurement system (ATGMS) is used at specific frequencies. The petition, which is similar to and based on information collected by Norfolk Southern during the Test Program, is pending FRA review.

NS is requesting to extend the Test Program until FRA issues a decision on the pending waiver petition or December 31, 2021, whichever is later. In support of its request, NS states that it will continue to comply with all other conditions and requirements of FRA's January 27, 2020, approval letter.

A copy of the petition, as well as any written communications concerning the petition, if any, are available for review online at *www.regulations.gov.*

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

• *Website: http://www.regulations.gov.* Follow the online instructions for submitting comments.

Communications received by September 7, 2021 will be considered by FRA before final action is taken. Comments received after that date will be considered if practicable. Anyone can search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). Under 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *https://www.transportation.gov/privacy.* See also *https://www.regulations.gov/privacy-notice* for the privacy notice of *regulations.gov.*

Issued in Washington, DC.

John Karl Alexy,

Associate Administrator for Railroad Safety, Chief Safety Officer.

[FR Doc. 2021–16440 Filed 7–30–21; 8:45 am]

BILLING CODE 4910–06–P

[1] *https://www.regulations.gov/document/FRA-2019-0099-0003* (Test Program); *https://www.regulations.gov/document/FRA-2019-0099-0001* (FRA's approval decision); *https://www.regulations.gov/document/FRA-2019-0099-0004* (FRA's published notice of approval).

[2] *See https://www.regulations.gov/document/FRA-2019-0099-0003.*

[3] *https://www.regulations.gov/document/FRA-2021-0044-0001.*

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–NEW]

Agency Information Collection Activity: 35% Exemption Request From 85/15 Reporting Requirement

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed new collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before October 1, 2021.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 1717 H Street NW, Washington, DC 20006, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–NEW'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to Section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on:

(1) Whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

Authority: Title 38 United States Code (U.S.C.) 3680A(d) and 38 Code of Federal Regulations (CFR) 21.4201.

Title: Exemption Request from 85/15 Reporting Requirement, VA Form 22–10216.

OMB Control Number: 2900–NEW.

Type of Review: New collection.

Abstract: This form will be used to satisfy requirements as outlined. The Department of Veterans Affairs (VA) is authorized to pay education benefits to Veterans and other eligible persons pursuing approved programs of education under chapters 30, 31, 32, 33, and 35 of title 38, U.S.C. and chapter 1606 of title 10, U.S.C.

As part of the benefits authorization process, Code of Federal Regulations (CR) Title 38 § 21.4201 places restrictions on enrollment based on the percentage of students receiving financial support in any approved program. Except as otherwise provided by regulation, VA shall not approve an enrollment in any course for an eligible Veteran, not already enrolled, for any period during which more than 85 percent of the students enrolled in the course are having all or part of their tuition fees or other charges paid for them by the educational institution or by VA under title 38, U.S.C., or under title 10, U.S.C. This is known as the 85/15Rule and is applicable to Institutions of Higher Learning (IHLs) and Non-College Degree postsecondary schools (NCDs).

The requirements apply to all courses, not otherwise exempt or waiver offered by all educational institutions, regardless whether the institution is degree-granting, proprietary profit, proprietary nonprofit, eleemosynary, public and/or tax-supported.

These schools are required to submit information necessary to determine if their programs of training are approved for the payment of VA educational assistance. This specified information is submitted either to VA or to the State Approving Agency (SAA) having jurisdiction over that school.

This regulation includes a provision that permits an exemption from routine reporting of this data for schools that assert the number of VA beneficiary students in all programs approved for GI Bill never exceeds 35% of the total enrollment at the educational institution. If approved, such schools must still monitor and collect the data, but are exempt from routinely reporting it to VA.

Affected Public: Individuals and households.

Estimated Annual Burden: 500 hours.

Estimated Average Burden per Respondent: 30 minutes.

Frequency of Response: Annually.

Estimated Number of Respondents: 1,000.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2021–16401 Filed 7–30–21; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee on Women Veterans, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act that the Advisory Committee on Women Veterans will conduct a virtual site visit on August 24–27, 2021, with the Veterans Integrated Service Network (VISN) 20: Northwest Network and the VA Portland Health Care System (VAPORHCS) in Portland, OR.

Date:	Time:	Location:
August 24, 2021	10:00 a.m.–2:30 p.m. (PT)	See Webex link and call-in information below.
August 25, 2021	10:00 a.m.–2:30 p.m. (PT)	See Webex link and call-in information below.
August 26, 2021	10:00 a.m.–2:00 p.m. (PT)	See Webex link and call-in information below.
August 27, 2021	10:00 a.m.–11:00 p.m. (PT)	See Webex link and call-in information below.

The purpose of the Committee is to advise the Secretary of Veterans Affairs regarding the needs of women Veterans with respect to health care, rehabilitation, compensation, outreach and other programs and activities administered by VA designed to meet such needs. The Committee makes recommendations to the Secretary regarding such programs and activities.

On Tuesday, August 24, the agenda includes overviews of: VISN 20's facilities and programs; an overview of VISN 20 services for women Veterans; and an overview of VAPORHCS facilities, programs and community partners.

On Wednesday, August 25, the agenda includes a continuation of briefings on VAPORHCS' programs and services for women Veterans. On Thursday, August 26, the agenda includes briefings on: Oregon State services and initiatives for women Veterans; an overview of Portland Regional Benefits Office's business lines and initiatives; and an overview of Willamette National Cemetery's services and programs.

On Friday, August 27, the committee will conduct an out-briefing with leadership from VISN 20, VAPORHCS, Portland Regional Benefits Office and Willamette National Cemetery. From 11:30 a.m.–12:30 p.m., the Committee will observe a women Veterans town hall meeting hosted by the VAPORHCS. The meeting sessions and town hall meeting are open to the public. Information about the town hall meeting will be provided to the public by the VAPORHCS.

No time will be allocated at this meeting for receiving oral presentations from the public. Interested parties should provide written comments for review by the Committee to Ms. Shannon L. Middleton at *00W@mail.va.gov* no later than August 13. Any member of the public who wishes to participate in the virtual site visit may use the following WebEx link: *https://veteransaffairs.webex.com/veteransaffairs/j.php?MTID=m0811fbff8f35b9c770c5d88657d99b68;* meeting number: 199 198 2364; password: aiPG43Znt*7. Participants can also join by phone (toll free) at 1–404–397–1596; access code: 199 198 2364##.

Dated: July 27, 2021.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2021–16371 Filed 7–30–21; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

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Part II

Department of Commerce

Bureau of Industry and Security

Publication of a Report on the Effect of Imports of Uranium on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended; Notice

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

RIN 0694–XC078

Publication of a Report on the Effect of Imports of Uranium on the National Security: An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, as Amended

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Publication of a report.

SUMMARY: The Bureau of Industry and Security (BIS) in this notice is publishing a report that summarizes the findings of an investigation conducted by the U.S. Department of Commerce (the ''Department'') pursuant to Section 232 of the Trade Expansion Act of 1962, as amended (''Section 232''), into the effect of imports of uranium on the national security of the United States. This report was completed on April 14, 2019 and posted on the BIS website in July 2021. BIS has not published the appendices to the report in this notification of report findings, but they are available online at the BIS website, along with the rest of the report (*see* the **ADDRESSES** section).

DATES: The report was completed on April 14, 2019. The report was posted on the BIS website in July 2021.

ADDRESSES: The full report, including the appendices to the report, are available online at *https://bis.doc.gov/232.*

FOR FURTHER INFORMATION CONTACT: For further information about this report contact Erika Maynard, Special Projects Manager, (202) 482–5572; and Leah Vidovich, Trade and Industry Analyst, (202) 482–1819. For more information about the Office of Technology Evaluation and the Section 232 Investigations, please visit: *http://www.bis.doc.gov/232.*

SUPPLEMENTARY INFORMATION:

The Effect of Imports of Uranium on the National Security

An Investigation Conducted Under Section 232 of the Trade Expansion Act of 1962, As Amended

U.S. Department of Commerce

Bureau of Industry and Security

Office of Technology Evaluation

April 14, 2019

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Prepared by Bureau of Industry and Security

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I. Executive Summary

This report summarizes the findings of an investigation conducted by the U.S. Department of Commerce (the ''Department'') pursuant to Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862 (''Section 232'')), into the effect of imports of uranium [1] on the national security of the United States.

In conducting this investigation, the Secretary of Commerce (the ''Secretary'') noted the Department's prior investigations under Section 232. This report incorporates the statutory analysis from the Department's 2018 reports on the imports of steel and aluminum [2] with respect to applying the

[1] *See* Figure 1 in Section IV, ''Product Scope of the Investigation,'' for the uranium products addressed by this report.

[2] U.S. Department of Commerce. Bureau of Industry and Security. *The Effect of Imports of Steel on the National Security* (Washington, DC: 2018) (''Steel Report'') and U.S. Department of Commerce. Bureau of Industry and Security. *The Effect of Imports of Aluminum on the National Security* (Washington, DC: 2018) (''Aluminum Report'').

https://www.bis.doc.gov/index.php/documents/steel/2224-the-effect-of-imports-of-steel-on-the-national-security-with-redactions-20180111/file.

terms ''national defense'' and ''national security'' in a manner that is consistent with the statute and legislative intent.[3]

As required by the statute, the Secretary considered all factors set forth in Section 232(d). In particular, the Secretary examined the effect of imports on national security requirements, specifically:

i. Domestic production needed for projected national defense requirements;

ii. the capacity of domestic industries to meet such requirements;

iii. existing and anticipated availabilities of the human resources, products, raw materials, and other supplies and services essential to the national defense;

iv. the requirements of growth of such industries and such supplies and services including the investment, exploration, and development necessary to assure such growth; and

v. the importation of goods in terms of their quantities, availabilities, character, and use as those affect such industries; and the capacity of the United States to meet national security requirements.

The Secretary also recognized the close relation of the economic welfare of the United States to its national security. Factors that can compromise the nation's economic welfare include, but are not limited to, the impact of ''foreign competition on the economic welfare of individual domestic industries; and any substantial unemployment, decrease in revenues of government, loss of skills, or any other serious effects resulting from the displacement of any domestic products by excessive imports.'' 19 U.S.C. 1862(d). In particular, this report assesses whether uranium is being imported ''in such quantities'' and ''under such circumstances'' as to ''threaten to impair the national security.''[4]

Findings

In conducting the investigation, the Secretary found:

A. Domestic Uranium Production Is Essential to U.S. National Security.[5]

1. Domestic uranium is required, based on U.S. policy and restrictions in international agreements on the use of most imported uranium, to satisfy the U.S. Department of Defense (DoD) requirements for maintaining effective military capabilities, including nuclear fuel for the U.S. Navy's fleet of 11 nuclear powered aircraft carriers and 70 nuclear powered submarines, source material for nuclear weapons, depleted uranium for ammunition, and other functions.

2. Uranium is also essential to maintaining U.S. critical infrastructure sectors, specifically the nation's 98 reactors for nuclear power generation to support the Nation's commercial power grid. Nuclear reactors supply 19 percent of U.S. electricity consumed in the U.S. and they support 15 of the 16 critical infrastructure sectors identified by the Department of Homeland Security (DHS).[6] Maintaining a robust civilian nuclear power industry is essential to U.S. national security, including both national defense and critical infrastructure requirements. DoD installations in the U.S. rely on the commercial power grid for 99 percent of their electricity needs.[7] The entire U.S. nuclear enterprise—weapons, naval propulsion, nonproliferation, enrichment, fuels services, and negotiations with international partners—depends on a robust U.S. civilian nuclear power industry.

3. Domestic uranium production and processing, referred to in this report as the ''front-end'' of the fuel cycle, depends on an economically viable, competitive U.S. commercial uranium industry.[8] The distinct stages of the U.S. nuclear fuel cycle extract uranium from the ground and ultimately transform it into fuel suitable for civilian nuclear power. The same stages of the U.S. nuclear fuel cycle are needed to fulfill national defense requirements for uranium used in naval nuclear fuel and tritium production in the future.

4. Since 1946, U.S. legislation governing the uranium production and nuclear power generation industries has consistently made explicit written reference to these industries' national security functions.[9]

B. Imports in Such Quantities as Presently Found Adversely Affect the Economic Welfare of the U.S. Uranium Industry

1. In 2018, almost all uranium used for civilian U.S. nuclear electric power generation was imported, totaling approximately 94 percent of consumption. Between 2009 and 2018, U.S. nuclear electric power generators increased their reliance on imported uranium products from 85.8 percent to 93.3 percent of their annual requirements.[10] In comparison, the Department's 1989 Section 232 investigation into ''The Effect of Imports of Uranium on the National Security'' found that imported uranium satisfied just 51 percent of U.S. nuclear electric power generators' requirements at that time.[11]

2. Uranium is imported into the United States in eight forms, with the two largest categories being uranium concentrate and enriched uranium. Uranium concentrate is primarily imported from Australia, Canada, Kazakhstan, and Uzbekistan. Enriched uranium is primarily imported from Russia, the United Kingdom, Germany, France, and the Netherlands.

3. Between 2014 and 2018, an average of 52 percent of U.S. nuclear electric power generator requirements of uranium concentrate was provided by Australia and Canada, 25 percent from Kazakhstan and Uzbekistan, and the remainder from Namibia (8.4 percent), Niger (2.5 percent), South Africa (2.2 percent), Malawi (1.4 percent), China (0.3 percent), and Russia (0.2 percent). The Department notes that between 2014 and 2018, an average of 24.2 percent of the uranium concentrate provided by Australian and Canadian

https://www.bis.doc.gov/index.php/documents/aluminum/2223-the-effect-of-imports-of-aluminum-on-the-national-security-with-redactions-20180117/file.

[3] Steel Report at 13–14; Aluminum Report at 12–13.

[4] 19 U.S.C. 1862(b)(3)(A).

[5] Domestic uranium production refers to all stages of the nuclear fuel cycle and their associated products, including uranium mining, uranium milling, uranium conversion, uranium enrichment, and nuclear fuel fabrication. Uranium mining and milling produce uranium concentrate, uranium conversion produces uranium hexafluoride (UF6), uranium enrichment produces enriched uranium product (EUP), and nuclear fuel fabrication produces finished nuclear fuel assemblies.

[6] U.S. White House. Office of the Press Secretary. *Critical Infrastructure Security and Resilience.* Presidential Policy Directive 21. (Washington, DC: 2013) https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil.

[7] U.S. Department of Defense. Office of the Undersecretary of Defense for Acquisition, Technology, and Logistics. *Report of the Defense Science Board Task Force on DoD Energy Strategy. (*Washington, DC: 2008), 18. *https://apps.dtic.mil/dtic/tr/fulltext/u2/a477619.pdf.*

[8] For the purposes of this report, the front-end industry is defined as companies owning or operating uranium mines, uranium mills, uranium converters, uranium enrichers, and nuclear fuel fabricators.

[9] Atomic Energy Act of 1946, as amended; Atomic Energy Act of 1954; 1964 Private Ownership of Special Nuclear Materials Act; The Energy Policy Act of 1992; The United States Enrichment Corporation Privatization Act of 1996.

[10] U.S. Energy Information Administration, ''Table S1a. Uranium purchased by owners and operators of U.S. civilian nuclear power reactors, 1994–2017'', *2017 Uranium Marketing Annual Report* (May 31, 2018), *https://www.eia.gov/uranium/marketing/pdf/umartableS1afigureS1.pdf.*

[11] U.S. Dept. of Commerce. Bureau of Export Administration; *The Effect of Imports of Uranium on the National Security;* 1989 (''1989 Report'') available at *https://www.bis.doc.gov/index.php/documents/section-232-investigations/88-uranium-1989/file.*

companies to U.S. nuclear power generators was originally sourced from Kazakhstan and Uzbekistan. In the same period, 20 percent of enrichment services purchased by U.S. utilities were from Russia. While a significant portion of imports come from Australia and Canada, the non-market practices of state-owned enterprises (SOEs) have similarly harmed the financial operations of uranium producers in these countries and threaten their continued ability to supply uranium mined in Australia or Canada to the U.S. market. China is also making steady strides to become a major supplier in the U.S. and global nuclear fuel market.

4. The entrance of China's state-owned nuclear fuel companies as potential actors in the global nuclear fuel industry will further intensify pressure on market economy producers in Canada, Australia, Europe, and the U.S. By 2020, China could have enrichment capacity beyond their domestic needs. U.S. utilities have reported purchases of uranium concentrate and enrichment services from Chinese controlled companies in the 2014–2018 period. China provided two percent of U.S. utilities' enrichment services contracts during this period, and is expected to supply even more in the coming years. Overall, the non-market business practices of Russia, Kazakhstan, Uzbekistan, and China's uranium industries continue to erode U.S. uranium mining and processing capacity.

5. Import competition from state-owned uranium enterprises has caused a significant atrophy in U.S. uranium infrastructure to the point where production levels from front-end companies are no longer economically sustainable. Documented declines in employment and skilled workforce (front-end employment is down 47 percent since 2009), as well as idling and closures of mining (13 since 2009), milling (only one of five remaining U.S. mills is presently active), and uranium conversion operations (the last U.S. facility is idled), demonstrate the steep decline in U.S. production capacity. Additionally, loss of long-term contracts with nuclear utilities, minimal market share, falling marginal net income, and a tenuous financial outlook indicate a moribund U.S. uranium industry.

C. Displacement of Domestic Uranium by Excessive Quantities of Imports Has the Serious Effect of Weakening Our Internal Economy

1. U.S. nuclear electric power utilities and uranium suppliers face multiple challenges. Federal Energy Regulatory Commission (FERC) market rules do not compensate nuclear power and other fuel-secure generation resources for their resilience value. In addition, subsidized renewable energy and lower natural gas prices are causing premature retirements of U.S. civilian nuclear power plants before the end of their useful lives. To cut costs and remain viable in distorted U.S. electricity markets, many nuclear power operators have ended long-term contracts with higher-priced U.S. uranium producers and turned to foreign SOEs for artificially low-priced uranium imports. The loss of long-term contracts, which provided the revenue stability needed to adequately support capital investment, research and development (R&D), and facility expansion, as well as to maintain workforce and production, has adversely impacted all elements of the U.S. uranium industry.

2. High dependence on uranium imports—averaging 93.3 percent of annual U.S. nuclear power utility consumption in 2018—has caused all elements of the U.S. uranium sector to shut down production capacity, struggle to maintain financial viability, reduce workforce, cut R&D, and slash capital expenditures. Excessive imports have dropped U.S. uranium mining production to some of the lowest levels seen since uranium mining began in the late 1940s.

3. Without a viable U.S. uranium industry, the United States cannot effectively respond to moderate or extended national security emergencies, or over the long-term meet the domestic uranium requirements of the U.S. Department of Defense. Moreover, U.S. nuclear electric power generators would not be able to operate at full capacity and would not be able to support critical infrastructure electric power needs if foreign nations, particularly Russia and other former Soviet states, chose to suspend or otherwise end uranium exports to the United States.

D. Uranium Market Distortion by State-Owned Enterprises Is a Circumstance That Contributes to the Weakening of the Domestic Economy

1. The 2011 Fukushima Daichii incident prompted the shutdown and/or idling of existing nuclear operators in Japan, Germany, and other countries. Additionally, many proposed nuclear reactors around the world, including in the United States, were cancelled. These actions decreased global demand for uranium, creating a supply glut and low uranium prices. This has severely affected the financial viability of U.S. uranium mining and milling in particular, as uranium imports have reached over 94 percent of U.S. utility consumption.

2. The Fukushima incident caused similar declines in other elements of the U.S. front-end nuclear fuel business, including conversion, enrichment, and fuel fabrication companies. [TEXT REDACTED] As of 2018, the total domestic front-end uranium industry employs 4,958 workers, compared to 9,232 workers in 2009, a decline of 47 percent.

3. During this same period SOEs in Russia, Kazakhstan, and Uzbekistan undercut U.S. uranium producers with lower priced uranium. SOEs in China also injected additional quantities of uranium into the marketplace despite lower prices and a drop in overall demand. In contrast, U.S. producers significantly cut production, shut down capacity, and shrank workforce levels.

4. Market economy uranium producers such as Australia, Canada, South Africa, France, Germany, the Netherlands, and the United Kingdom have also been forced to curtail or suspend operations due to the excess production by SOE uranium producers that has depressed global uranium prices. SOE competition has displaced demand for Canadian and Australian product. Between 2016 and 2017, Canada cut back domestic production approximately 6.6 percent. Australia reduced output by 6.9 percent. In contrast, Russia and Kazakhstan decreased their production by only 5.1 and 2.9 percent, respectively; but China increased production by 16 percent. Uzbekistan made no production cuts.

5. U.S. nuclear electric power generators maintain only a limited amount of nuclear fuel materials in reserve to address potential supply disruptions. The U.S. Government maintains only a small stockpile of enriched uranium for utility use in the event of a fuel supply disruption. U.S. nuclear electric power generators are therefore vulnerable to sudden and extended disruptions in the nuclear fuel supply chain, especially product supplied through Russia and Kazakhstan.

Conclusion

Based on these findings, the Secretary of Commerce has concluded that the present quantities and circumstance of uranium imports are ''weakening our internal economy'' and ''threaten to impair the national security'' as defined in Section 232. An economically viable, secure supply of U.S.-sourced uranium is required for national defense needs. International obligations, including agreements with foreign partners under Section 123 of the Atomic Energy Act of

1954, govern the use of most imported uranium and typically restrict it to peaceful, non-explosive uses. As a result, uranium used for military purposes must generally be domestically produced from mining through the fuel fabrication process. Furthermore, the predictable maintenance and support of U.S. critical infrastructure, especially the electric power grid, depends on a diverse supply of uranium, which includes U.S.-sourced uranium products and services.

The Secretary further recognizes that the U.S. uranium industry's financial and production posture has significantly deteriorated since the Department's 1989 Report. That investigation noted that U.S. nuclear power utilities imported 51.1 percent of their uranium requirements in 1987. By 2018, imports had increased to 93.3 percent of those utilities' annual requirements. Based on comprehensive 2019 industry data provided by U.S. uranium producers and U.S. nuclear electric power utilities to the Department in response to a mandatory survey, U.S. utilities' usage of U.S. mined uranium has dropped to nearly zero. [TEXT REDACTED] Based on the current and projected state of the U.S. uranium industry, the Department has concluded that the U.S. uranium industry is unable to satisfy existing or future national security needs or respond to a national security emergency requiring a large increase in domestic uranium production.

Absent immediate action, closures of the few remaining U.S. uranium mining, milling, and conversion facilities are anticipated within the next few years. Further decreases in U.S. uranium production and capacity, including domestic fuel fabrication, will cause even higher levels of U.S. dependence on imports, especially from Russia, Kazakhstan, Uzbekistan, and China. Increased imports from SOEs in those countries, and in particular Russia and China, which the 2017 National Security Strategy noted present a direct challenge to U.S. influence, are detrimental to the national security.[12] The high risk of loss of the remaining U.S. domestic uranium industry if the present excessive level of imports continue threatens to impair the national security as defined by Section 232.

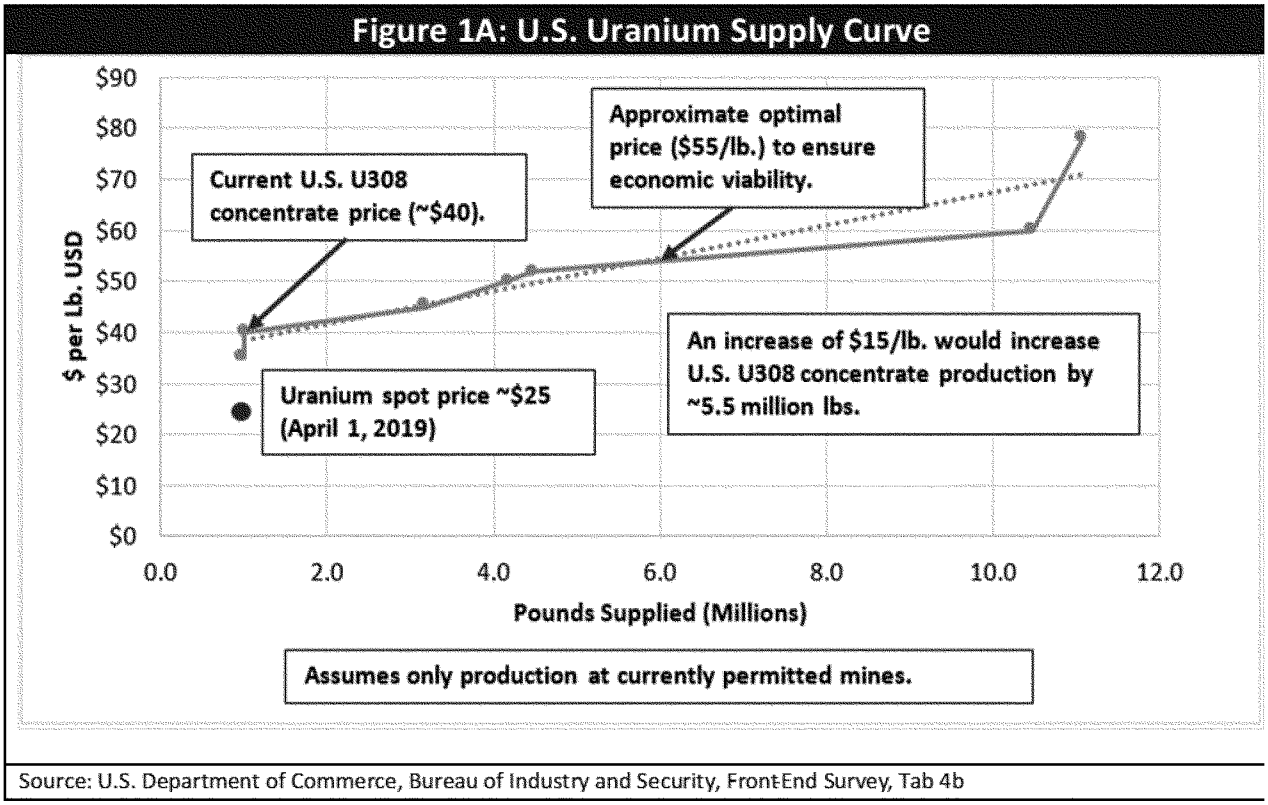
The Secretary has determined that to remove the threat of impairment to national security, it is necessary to reduce imports of uranium to a level that enables U.S. uranium producers to return to an economically competitive and financially viable position. This will allow the industry to sustain production capacity, hire and maintain a skilled workforce, make needed capital expenditures, and perform necessary research and development activities. A modest reduction of uranium imports will allow for the revival of U.S. uranium mining and milling, the restart of the sole U.S. uranium converter, and a reduction in import challenges to fuel fabricators, while also recognizing the market and pricing challenges confronting the U.S. nuclear power utilities.

Recommendation

Due to the threat to the national security, as defined in Section 232, from excessive uranium imports, the Secretary recommends that the President take immediate action by adjusting the level of these imports through the implementation of an import waiver to achieve a phased-in reduction of uranium imports. The reduction in imports of uranium should be sufficient to enable U.S. producers to recapture and sustain a market share of U.S. uranium consumption that will allow for financial viability, and would enable the maintenance of a skilled workforce and the production capacity and uranium output needed for national defense and critical infrastructure requirements. The reduction imposed should be sufficient to enable U.S. producers to eventually supply 25 percent of U.S. utilities' uranium needs based on 2018 U.S. U308 concentrate annual consumption requirements.

Based on the survey responses, the Department has determined that U.S. uranium producers require an amount equivalent to 25 percent of U.S. nuclear power utilities' 2018 annual U308 concentrate consumption to ensure financial viability. Based on the Department's analysis, if U.S.-mined uranium supplied 25 percent of U.S. nuclear power utilities' annual U308 concentrate consumption, U.S. uranium prices will increase to approximately $55 per pound (*see* Figure 1A). The current spot price is low due to distortions from SOEs.

[12] U.S. White House Office. *National Security Strategy of the United States of America.* (Washington, DC: 2017), 2 *https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905-2.pdf.*



The $55 per pound price will increase mine capacity to the point where U.S. uranium mines can supply approximately 6 million pounds of uranium concentrate per year, which is approximately 25 percent of U.S. nuclear power utilities' consumption for U308 concentrate in any given year.

The Secretary recommends that the import reduction be phased in over a five-year period. This will allow U.S. uranium mines, mills, and converters to reopen or expand closed or idled facilities; hire, train and maintain a skilled workforce; and make necessary investments in new capacity. This phased-in approach will also allow U.S. nuclear power utilities time to adjust and diversify their fuel procurement contracts to reintroduce U.S. uranium into their supply chains.

The Secretary recommends that either a targeted or global quota be used to adjust the level of imports and that such quota should be in effect for a duration sufficient to allow the necessary time needed to stabilize and revitalize the U.S. uranium industry. According to survey responses, the average time to restart an idle uranium production facility is two to five years, and several additional years are needed to add new capacity. Market certainty, which can be provided by long-term contracts with U.S. nuclear power utilities, is needed to build cash flow, pay down debt, and raise capital for site modernization; workforce recruitment; and to conduct environmental and regulatory reviews.

Option 1—Targeted Zero Quota

This targeted zero quota option would prohibit imports of uranium from Kazakhstan, Uzbekistan, and China (the ''SOE countries'') to enable U.S. uranium producers to supply approximately 25 percent of U.S. nuclear power utility consumption. A U.S. nuclear power utility or other domestic user would be eligible for a waiver that allows the import of uranium from the SOE countries, with any import of uranium from Russia subject to the Russian Suspension Agreement, after such utility or user files appropriate documentation with the Department. In the case of a U.S. nuclear power utility, the documentation must show that such utility has a contract or contracts to purchase for their consumption on an annual basis not less than the percentage of U.S. produced uranium U308 concentrate shown in the phase-in table below.

PERCENT OF ANNUAL U308 CONCENTRATE CONSUMPTION REQUIRED TO BE SOURCED FROM THE U.S.

Year	2020	2021	2022	2023	2024 and beyond
Percent of Annual U308 Concentrate Consumption Required to be Sourced from the U.S.	5	10	15	20	25

Phased-in incrementally over five years, this option will help facilitate the reopening and expansion of U.S. uranium mining, milling, and conversion facilities, and will ensure that U.S. uranium producers can make investments required for future financial viability without causing unintentional harm to other market economy uranium producers. This option avoids undue financial harm to U.S. nuclear power utilities by affording them sufficient time to adjust their fuel procurement strategies.

The zero quota on uranium imports from SOE countries would not apply to

uranium imports from SOE countries for use by U.S. milling, conversion, enrichment, and fuel fabrication services that produce uranium products for export from the United States. A U.S. milling, conversion, enrichment, or fuel fabricator seeking to import uranium from an SOE country for use to produce uranium products for export would need to file appropriate documentation with the Department to obtain a waiver for the import of such uranium for export.

The Secretary believes that this option to impose a zero quota for imports of uranium from SOE countries, while continuing to allow unrestricted importation of uranium from Canada, Australia, and EURATOM [13] member countries based on their security and economic relationships with the United States, should address the threatened impairment of U.S. national security. This would be accomplished by promoting the economic revival of the U.S. uranium industry, so long as there is not significant transshipment or reprocessing of SOE country uranium through these unrestricted countries.

The Department will monitor these unrestricted imports to ensure there is not significant transshipment, reprocessing, or book transfers from SOE countries to unrestricted countries in an attempt to circumvent and undermine the U.S. uranium producers' ability to provide 25 percent of U.S. annual U308 concentrate consumption. Many companies in unrestricted countries supply uranium sourced from SOE countries. Consequently, up to one-third of the materials delivered to U.S. nuclear power utilities, at this time, is not sourced directly from the country of import.

Imports of uranium from Russia under a waiver would also be subjected to the Russian Suspension Agreement. This option assumes that such agreement will continue to be in effect over the relevant time period and would apply to any Russian uranium imports by U.S. nuclear power utilities, thus holding Russian uranium imports to their current level of approximately 20 percent of U.S. enrichment demand. In the event that the Russian Suspension Agreement is not extended and terminates, then the Secretary recommends that a quota on uranium imports under a waiver of Russian Uranium Products (as defined in the Russian Suspension Agreement) of up to 15 percent of U.S. enrichment demand be imposed. If adopted this quota would be administered by the Department in the same manner as the Russian Suspension Agreement is presently administered.

The adjustment of imports proposed under this option would be in addition to any applicable antidumping or countervailing duties collections.

To complement the proposed trade action, the Secretary recommends that the Federal Energy Regulatory Commission (FERC) should act promptly to ensure that regulated wholesale power market regulations adequately compensate nuclear and other fuel-secure generation resources. Specifically, FERC should determine whether current market rules, which discriminate against secure nuclear fuel generation resources in favor of intermittent resources, such as natural gas, solar, and wind, result in unjust, unreasonable, and unduly discriminatory rates that distort energy markets, harm consumers, and undermine electric reliability. If so, FERC should consider taking appropriate action to ensure that rates are just and reasonable.

The Department of Commerce, in consultation with other appropriate departments and agencies, will monitor the status of the U.S. uranium industry and the effectiveness of this remedy and will make recommendations to the President regarding whether it should be modified, extended, or terminated.

Option 2—Global Zero Quota

This option would establish a zero quota on imports of uranium from all countries until specific conditions are met to enable U.S. producers to supply 25 percent of U.S. nuclear power utilities' annual consumption of uranium U308 concentrate. A U.S. nuclear power utility or other domestic user would be eligible for a waiver to import uranium from any country after submitting appropriate documentation to the Department. In the case of a U.S. nuclear power utility, the documentation must show that such utility has a contract or contracts to purchase for their consumption on an annual basis not less than the percentage of U.S. produced uranium U308 concentrate shown in the phase-in table below.

PERCENT OF ANNUAL U308 CONCENTRATE CONSUMPTION REQUIRED TO BE SOURCED FROM THE U.S.

Year	2020	2021	2022	2023	2024 and beyond
Percent of Annual U308 Concentrate Consumption Required to be Sourced from the U.S.	5	10	15	20	25

Phased-in incrementally over five years, this option will help facilitate the reopening and expansion of U.S. uranium mining, milling, and conversion facilities, and will ensure that U.S. uranium producers can make investments required for future financial viability. This option avoids undue financial harm to U.S. nuclear power utilities by affording them sufficient time to adjust their fuel procurement strategies.

The zero quota on uranium imports would not apply to uranium imports for use by U.S. milling, conversion, enrichment, and fuel fabrication services that produce uranium products for export from the United States. A U.S. milling, conversion, enrichment, or fuel fabricator seeking to import uranium for use to produce uranium products for export would need to file appropriate documentation with the Department to obtain a waiver for the import of uranium.

The Department will provide adequate time for U.S. industry to receive a waiver prior to a zero quota being implemented globally. Based on information received during the investigation, the Department believes that this option will not cause undue burdens.

The Secretary believes that this option to impose a zero quota for imports of uranium will address the threatened impairment of U.S. national security by promoting the economic revival of the U.S. uranium industry. This option also prevents the possibility of transshipment of SOE overproduction through third countries and avoids

[13] As of April 2019, EURATOM includes all 28 members of the European Union. The United Kingdom will cease to be a member of EURATOM if and when it leaves the European Union. Should the United Kingdom cease to be a member of EURATOM, the same preferential treatment given to EURATOM members will also be applied to the United Kingdom.

undue harm to U.S. enrichment and fuel fabrication export operations. These domestic export operations rely on an ability to access working uranium stock regardless of the specific mining origin of a given uranium-based material.

Tennessee Valley Authority (TVA) purchases of Canadian UO_3 natural uranium diluent in its execution of the National Nuclear Security Administration's current highly-enriched uranium (HEU) down-blending campaign would be excluded from the zero quota on imports of uranium. In addition, any transfer pursuant to a Mutual Defense Agreement that references special nuclear material would be excluded from the zero quota on imports of uranium.

Imports of uranium from Russia under a waiver would also be governed by the Russian Suspension Agreement. This option assumes that such agreement will continue to be in effect over the relevant time period and would apply to any Russian uranium imports by U.S. nuclear power utilities, thus holding Russian uranium imports to their current level of approximately 20 percent of U.S. enrichment demand. In the event that the Russian Suspension Agreement is not extended and terminates, then the Secretary recommends that a quota on uranium imports under a waiver of Russian Uranium Products (as defined in the Russian Suspension Agreement) of up to 15 percent of U.S. enrichment demand be imposed. If adopted, this quota would be administered by the Department in the same manner as the Russian Suspension Agreement is presently administered.

The adjustment of imports proposed under this option would be in addition to any applicable antidumping or countervailing duties collections.

To complement the proposed trade action, the Secretary recommends that the Federal Energy Regulatory Commission (FERC) should act promptly to ensure that regulated wholesale power market regulations adequately compensate nuclear and other fuel-secure generation resources. Specifically, FERC should determine whether current market rules, which discriminate against secure nuclear fuel generation resources in favor of intermittent resources, such as natural gas, solar, and wind, result in unjust, unreasonable, and unduly discriminatory rates that distort energy markets, harm consumers, and undermine electric reliability. If so, FERC should consider taking appropriate action to ensure that rates are just and reasonable.

The Department of Commerce, in consultation with other appropriate departments and agencies, will monitor the status of the U.S. uranium industry and the effectiveness of this remedy to determine if it should be modified, extended, or terminated.

Option 3—Alternative Action

Should the President determine that the threatened impairment of national security does not warrant immediate adjustment of uranium imports at this time but that alternative action should be taken to improve the condition of the U.S. uranium industry to enable the U.S. industry to supply 25 percent of U.S nuclear power utilities annual consumption of uranium U308 concentrate, the President could direct the Department of Defense (DOD) and the Department of Energy (DOE) to report to the President within 90 days on options for increasing the economic viability of the domestic uranium mining industry. The report should include, but not be limited to, recommendations for: (1) The elimination of regulatory constraints on domestic producers; (2) incentives for increasing investment; and (3) ways to work with likeminded allies to address unfair trade practices by SOE countries, including through trade remedy actions and the negotiation of new rules and best practices. The President could also direct the United States Trade Representative to enter into negotiations with the SOE countries to address the causes of excess uranium imports that threaten the national security.

To complement the proposed alternative action, the Secretary recommends that the Federal Energy Regulatory Commission (FERC) should act promptly to ensure that regulated wholesale power market regulations adequately compensate nuclear and other fuel-secure generation resources. Specifically, FERC should determine whether current market rules, which discriminate against secure nuclear fuel generation resources in favor of intermittent resources, such as natural gas, solar, and wind, result in unjust, unreasonable, and unduly discriminatory rates that distort energy markets, harm consumers, and undermine electric reliability. If so, FERC should consider taking appropriate action to ensure that rates are just and reasonable.

The Department of Commerce, in consultation with other appropriate departments and agencies, will monitor the status of the U.S. uranium industry and the effectiveness of this remedy and recommend to the President if any additional measures are needed. Alternatively, the Secretary may initiate another investigation under Section 232.

The Secretary also makes public policy recommendations for additional measures that complement these three options.

II. Legal Framework

A. Section 232 Requirements

Section 232 provides the Secretary with the authority to conduct investigations to determine the effect on the national security of the United States of imports of any article. It authorizes the Secretary to conduct an investigation if requested by the head of any department or agency, upon application of an interested party, or upon his own motion. *See* 19 U.S.C. 1862(b)(1)(A).

Section 232 directs the Secretary to submit to the President a report with recommendations for ''action or inaction under this section'' and requires the Secretary to advise the President if any article ''is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A).

Section 232(d) directs the Secretary and the President to, in light of the requirements of national security and without excluding other relevant factors, give consideration to the domestic production needed for projected national defense requirements and the capacity of the United States to meet national security requirements. *See* 19 U.S.C. 1862(d).

Section 232(d) also directs the Secretary and the President to ''recognize the close relation of the economic welfare of the Nation to our national security, and . . . take into consideration the impact of foreign competition on the economic welfare of individual domestic industries'' by examining whether any substantial unemployment, decrease in revenues of government, loss of skills or investment, or other serious effects resulting from the displacement of any domestic products by excessive imports, or other factors, results in a ''weakening of our internal economy'' that may impair the national security.[14] *See* 19 U.S.C. 1862(d).

Once an investigation has been initiated, Section 232 mandates that the Secretary provide notice to the Secretary of Defense that such an investigation has been initiated. Section 232 also

[14] An investigation under Section 232 looks at excessive imports for their threat to the national security, rather than looking at unfair trade practices as in an antidumping investigation.

requires the Secretary to do the following:

(1) ''Consult with the Secretary of Defense regarding the methodological and policy questions raised in [the] investigation;''

(2) ''Seek information and advice from, and consult with, appropriate officers of the United States;'' and

(3) ''If it is appropriate and after reasonable notice, hold public hearings or otherwise afford interested parties an opportunity to present information and advice relevant to such investigation.'' [15] *See* 19 U.S.C. 1862(b)(2)(A)(i)–(iii).

As detailed in the report, all of the requirements set forth above have been satisfied.

In conducting the investigation, Section 232 permits the Secretary to request that the Secretary of Defense provide an assessment of the defense requirements of the article that is the subject of the investigation. *See* 19 U.S.C. 1862(b)(2)(B).

Upon completion of a Section 232 investigation, the Secretary is required to submit a report to the President no later than 270 days after the date on which the investigation was initiated. *See* 19 U.S.C. 1862(b)(3)(A). The report must:

(1) Set forth ''the findings of such investigation with respect to the effect of the importation of such article in such quantities or under such circumstances upon the national security;''

(2) Set forth, ''based on such findings, the recommendations of the Secretary for action or inaction under this section;'' and

(3) ''If the Secretary finds that such article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security . . . so advise the President . . . *See* 19 U.S.C. 1862(b)(3)(A).

All unclassified and non-proprietary portions of the report submitted by the Secretary to the President must be published.

Within 90 days after receiving a report in which the Secretary finds that an article is being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security, the President shall:

(1) ''Determine whether the President concurs with the finding of the Secretary''; and

(2) ''If the President concurs, determine the nature and duration of the action that, in the judgment of the President, must be taken to adjust the imports of the article and its derivatives so that such imports will not threaten to impair the national security'' (*see* 19 U.S.C. 1862(c)(1)(A)).

B. Discussion

While Section 232 does not specifically define ''national security,'' both Section 232, and the implementing regulations at 15 CFR part 705, contain non-exclusive lists of factors that the Secretary must consider in evaluating the effect of imports on the national security. Congress in Section 232 explicitly determined that ''national security'' includes, but is not limited to, ''national defense'' requirements. *See* 19 U.S.C. 1862(d)).

The Department in 2001 determined that ''national defense'' includes both defense of the United States directly and the ''ability to project military capabilities globally.'' [16] The Department also concluded in 2001 that, ''In addition to the satisfaction of national defense requirements, the term ''national security'' can be interpreted more broadly to include the general security and welfare of certain industries, beyond those necessary to satisfy national defense requirements, which are critical to the minimum operations of the economy and government.'' The Department called these ''critical industries.'' [17] This report once again uses these reasonable interpretations of 'national defense'' and ''national security.'' However, this report uses the more recent 16 critical infrastructure sectors identified in Presidential Policy Directive 21 [18] instead of the 28 industry sectors used by the Bureau of Export Administration in the 2001 Report.[19]

Section 232 directs the Secretary to determine whether imports of any article are being made ''in such quantities'' or ''under such circumstances'' that those imports ''threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A). The statutory construction makes clear that either the quantities or the circumstances, standing alone, may be sufficient to support an affirmative finding. They may also be considered together, particularly where the circumstances act to prolong or magnify the impact of the quantities being imported.

The statute does not define a threshold for when ''such quantities'' of imports are sufficient to threaten to impair the national security, nor does it define the ''circumstances'' that might qualify.

Likewise, the statute does not require a finding that the quantities or circumstances are impairing the national security. Instead, the threshold question under Section 232 is whether those quantities or circumstances ''threaten to impair the national security.'' *See* 19 U.S.C. 1862(b)(3)(A). This makes evident that Congress expected an affirmative finding under Section 232 before an actual impairment of the national security. [20]

Section 232(d) contains a list of factors for the Secretary to consider in determining if imports ''threaten to impair the national security''[21] of the United States, and this list is mirrored in the implementing regulations. *See* 19 U.S.C. 1862(d) and 15 CFR 705.4. Congress was careful to note twice in Section 232(d) that the list provided, while mandatory, is not exclusive.[22] Congress' illustrative list is focused on the ability of the United States to maintain the domestic capacity to provide the articles in question as needed to maintain the national security of the United States.[23] Congress broke

[15] Department regulations (i) set forth additional authority and specific procedures for such input from interested parties, *see* 15 CFR 705.7 and 705.8, and (ii) provide that the Secretary may vary or dispense with those procedures ''in emergency situations, or when in the judgment of the Department, national security interests require it.'' *Id.,* 705.9.

[16] Department of Commerce, Bureau of Export Administration; *The Effects of Imports of Iron Ore and Semi-Finished Steel on the National Security;* Oct. 2001 (''2001 Iron and Steel Report'') at 5.

[17] *Id.*

[18] Presidential Policy Directive 21; *Critical Infrastructure Security and Resilience;* February 12, 2013 (''PPD–21'').

[19] *See Op. Cit.* at 16.

[20] The 2001 Iron and Steel Report used the phrase ''fundamentally threaten to impair'' when discussing how imports may threaten to impair national security. *See* 2001 Iron and Steel Report at 7 and 37. Because the term ''fundamentally'' is not included in the statutory text and could be perceived as establishing a higher threshold, the Secretary expressly does not use the qualifier in this report. The statutory threshold in Section 232(b)(3)(A) is unambiguously ''threaten to impair'' and the Secretary adopts that threshold without qualification. 19 U.S.C. 1862(b)(3)(A).

[21] 19 U.S.C. 1862(b)(3)(A).

[22] *See* 19 U.S.C. 1862(d) (''the Secretary and the President shall, in light of the requirements of national security and without excluding other relevant factors . . .'' and ''serious effects resulting from the displacement of any domestic products by excessive imports shall be considered, without excluding other factors . . .'').

[23] This reading is supported by Congressional findings in other statutes. *See, e.g.,* 15 U.S.C. 271(a)(1)(''The future well-being of the United States economy depends on a strong manufacturing base . . . '') and 50 U.S.C. 4502(a)(''Congress finds that—(1) the security of the United States is dependent on the ability of the domestic industrial base to supply materials and services . . . (2)(C) to provide for the protection and restoration of domestic critical infrastructure operations under emergency conditions . . . (3) . . . the national defense preparedness effort of the United States

Continued

the list of factors into two equal parts using two separate sentences. The first sentence focuses directly on ''national defense'' requirements, thus making clear that ''national defense'' is a subset of the broader term ''national security.'' The second sentence focuses on the broader economy and expressly directs that the Secretary and the President ''shall recognize the close relation of the economic welfare of the Nation to our national security.'' [24] *See* 19 U.S.C. 1862(d).

In addition to ''national defense'' requirements, two of the factors listed in the second sentence of Section 232(d) are particularly relevant in this investigation. Both are directed at how ''such quantities'' of imports threaten to impair national security *See* 19 U.S.C. 1862(b)(3)(A). In administering Section 232, the Secretary and the President are required to ''take into consideration the impact of foreign competition on the economic welfare of individual domestic industries'' and any ''serious effects resulting from the displacement of any domestic products by excessive imports'' in ''determining whether such weakening of our internal economy may impair the national security.'' *See* 19 U.S.C. 1862(d).

Another factor, not on the list, that the Secretary found to be relevant is the presence of global excess supply of uranium. This excess supply results in uranium imports occurring ''under such circumstances'' that they threaten to impair the national security. *See* 19 U.S.C. 1862(b)(3)(A). The Secretary considers excess global uranium supply as a relevant circumstance because state-owned enterprises have maintained or increased uranium production, and reduced prices, notwithstanding declining market conditions. At the same time, market producers, including U.S. producers, have decreased production under these market conditions. This excess supply means that U.S. uranium producers, for the foreseeable future, face increasing competition from state-owned uranium producers as well as foreign market-based competitors.

After careful examination of the facts in this investigation, the Secretary has concluded that excessive imports of uranium in the present circumstances are weakening our internal economy and threaten to impair the national security as defined in Section 232. Several important factors support this conclusion, including the global excess uranium supply due to non-market based production by state-owned enterprises, the resulting near total dependence of U.S. nuclear power production on uranium imports, and the impact that the loss of a domestic U.S. uranium production capacity and workforce would have on the nation's ability to respond to potential national emergencies.

III. Investigation Process

A. Initiation of Investigation

On January 16, 2018, Energy Fuel Resources (US) Inc. and UR-Energy USA Inc. (hereafter ''Petitioners'') petitioned the Secretary to conduct an investigation under Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862), to determine the effect of imports of uranium on the national security.

Upon receipt of the petition, the Department carefully reviewed the material facts outlined in the petition. Initial discussions were held with other bureaus within the Department of Commerce as well as with other interested parties at the Departments of Defense and Energy. Legal counsel at the Department also carefully reviewed the petition to ensure it met the requirements of the Section 232 statute and the implementing regulations. Subsequently, on July 18, 2018, the Department accepted the petition and initiated the investigation. Pursuant to Section 232(b)(1)(b), the Department notified the U.S. Department of Defense with a July 18, 2018 letter from Secretary Ross to the Secretary of Defense, James Mattis (*see* Appendix A).

On July 25, 2018, the Department published a **Federal Register** Notice (*see* Appendix B—**Federal Register**, Vol. 83, No. 143, 35,204–35,205) announcing the initiation of an investigation to determine the effect of imports of uranium on the national security. The notice also announced the opening of the public comment period.

B. Public Comments

On July 25, 2018, the Department invited interested parties to submit written comments, opinions, data, information, or advice relevant to the criteria listed in Section 705.4 of the National Security Industrial Base Regulations (15 CFR 705.4) as they affect the requirements of national security, including the following:

(a) Quantity of the articles subject to the investigation and other circumstances related to the importation of such articles;

(b) Domestic production capacity needed for these articles to meet projected national defense requirements;

(c) The capacity of domestic industries to meet projected national defense requirements;

(d) Existing and anticipated availability of human resources, products, raw materials, production equipment, facilities, and other supplies and services essential to the national defense;

(e) Growth requirements of domestic industries needed to meet national defense requirements and the supplies and services including the investment, exploration and development necessary to assure such growth;

(f) The impact of foreign competition on the economic welfare of any domestic industry essential to our national security;

(g) The displacement of any domestic products causing substantial unemployment, decrease in the revenues of government, loss of investment or specialized skills and productive capacity, or other serious effects;

(h) Relevant factors that are causing or will cause a weakening of our national economy; and

(i) Any other relevant factors.

The public comment period was originally scheduled to end on September 10, 2018. Following requests from the general public, the Department extended the deadline from September 10 to September 25 (*see* Appendix B—**Federal Register** Vol. 83, No. 175, 45,595–45,596). The Department received 1,019 written submissions concerning this investigation. Representative samples were grouped together then 837 comments were posted on *Regulations.gov* for public review. Parties who submitted comments included firms representing all parts of the nuclear fuel cycle, representatives of U.S. federal, state and local governments, foreign governments, as well as other concerned organizations. All public comments were carefully reviewed and factored into the investigative process. The public comments of key stakeholders are summarized in Appendix C, along

government requires—(C) the development of domestic productive capacity to meet—(ii) unique technological requirements . . . (7) much of the industrial capacity that is relied upon by the United States Government for military production and other national defense purposes is deeply and directly influenced by—(A) the overall competitiveness of the industrial economy of the United States; and (B) the ability of industries in the United States, in general, to produce internationally competitive products and operate profitably while maintaining adequate research and development to preserve competitiveness with respect to military and civilian production; and (8) the inability of industries in the United States, especially smaller subcontractors and suppliers, to provide vital parts and components and other materials would impair the ability to sustain the Armed Forces of the United States in combat for longer than a short period.'').

[24] *Accord* 50 U.S.C. 4502(a).

with a link to the docket (BIS–2018–0011) where all public comments can be viewed in full on *Regulations.gov*.

Due to the limited number of firms engaged in the U.S. uranium industry and in nuclear power generation, it was determined that a public hearing was not necessary in order to conduct a comprehensive investigation. In lieu of holding a public hearing on this investigation, the Department issued two separate mandatory surveys (*see* Appendix D and Appendix E) to participants in the U.S. front-end uranium industry and the U.S. nuclear power generation sector, which collected both qualitative and quantitative information. The front-end survey was sent to 34 companies engaged in uranium mining and milling, uranium concentrate production, uranium enrichment, and nuclear fuel fabrication. The nuclear power generation survey was sent to all 24 operators of U.S. nuclear power plants and covered 98 reactors.

The surveys provided an opportunity for organizations to disclose confidential and non-public information needed by the Department to conduct a thorough investigation. These mandatory surveys were conducted using statutory authority pursuant to Section 705 of the Defense Production Act of 1950, as amended (50 U.S.C. 4555), and collected detailed information concerning factors such as imports/exports, production, capacity utilization, employment, operating status, global competition, and financial information. The resulting aggregate data provided the Department with detailed industry information that was otherwise not publicly available and was needed to effectively conduct analysis for this investigation.

Responses to the Department's surveys were required by law (50 U.S.C. 4555). Information furnished in the survey responses is deemed confidential and will not be published or disclosed except in accordance with Section 705 of the DPA. Section 705 of the DPA prohibits the publication or disclosure of this information unless the President determines that the withholding of such information is contrary to the interest of the national defense. Information will not be shared with any non-government entity other than in aggregate form.

C. Site Visits and Information Gathering Activities

To obtain additional information on the U.S. uranium industry and the U.S. nuclear power generation sector, the Department conducted site visits to several uranium and nuclear power generation facilities:

1) Calvert Cliffs Nuclear Power Plant in Lusby, Maryland. This is a double reactor facility.

2) Three uranium mines: La Sal (Utah—Conventional Mine), Nichols Ranch (Wyoming—In Situ facility), and Lost Creek (Wyoming—In Situ facility).

(3) White Mesa Mill in Blanding, Utah. This facility is the only fully-licensed and operating conventional uranium mill in the U.S.

In order to gain insights into the U.S. uranium industry's challenges, information gathering activities and meetings were held with representatives of domestic and international uranium producers, associations, power generators, foreign governments, and others interested parties.

D. Interagency Consultation

The Department consulted with the Department of Defense including the Office of Industrial Base, Defense Logistics Agency, and the Department of the Navy regarding methodological and policy questions that arose during the investigation.

The Department also consulted with other U.S. Government agencies with expertise and information regarding the uranium industry including the Department of Energy, the Energy Information Administration, the National Nuclear Security Administration, the International Trade Administration, the Department of State, the Office of the United States Trade Representative, the Nuclear Regulatory Commission, the U.S. Geological Survey, and the Federal Energy Regulatory Commission.

E. Review of the Department of Commerce 1989 Section 232 Investigation on Uranium Imports

The Department reviewed the previous Section 232 Investigation on the Effect of Uranium Imports on National Security from September 1989. This investigation, requested by the Secretary of Energy, determined that U.S. utilities imported a significant share of their uranium requirements. In 1987, U.S. utilities imported approximately 51.1 percent of their requirements, and the investigation projected that this level would reach 70.8 percent by 1993.[25] The 1989 investigation also found that U.S. uranium producers faced strong foreign competition, particularly from the Soviet Union. It further reported that employment in the domestic industry was steadily decreasing.[26]

[TEXT REDACTED][27] Consequently, the Secretary concluded that uranium was not being imported into the United States under such quantities or circumstances that threatened to impair the national security.

The Department took note of the methodologies and analytic approaches used to conduct the 1989 investigation and evaluated its findings and conclusion in light of the current state of the U.S. uranium industry. Further discussion of the September 1989 Section 232 Investigation is in Appendix G.

IV. Product Scope of the Investigation

The scope of this investigation defined uranium products at the Harmonized Tariff Schedule of the United States (HTS) 10-digit level. The eight product categories and related HTS codes covered by this report (*see* Figure 1B) are produced by U.S. uranium companies engaged in the nuclear fuel cycle, and are imported for use by U.S. nuclear power operators. Detailed information was collected in the Department's survey responses from U.S. uranium producers and U.S. nuclear power operators regarding products covered by the HTS codes. These products are used in, or otherwise support, various national defense and critical infrastructure applications.

[25] 1989 Report, Letter Requesting 232 Investigation, also III–21.

[26] 1989 Report, III–2, III–25.

[27] Ibid., V–4 to V–5.

FIGURE 1B: URANIUM PRODUCT SCOPE OF THE INVESTIGATION

Heading/subheading/product	10 Digit HTS code
Imports of uranium ores and concentrates, natural uranium compounds, and all forms of enriched uranium:	
• Uranium Ore and Concentrates	2612.10.00.00
• Uranium Compounds (Oxide, Hexafluoride, and Other)	Oxide 2844.10.20.10 Hexafluoride 2844.10.20.25 Other 2844.10.20.55
• Uranium enriched in U235 and its compounds; alloys, dispersions (including cermets), ceramic products and mixtures containing uranium enriched in U235.	Oxide 2844.20.00.10 Hexafluoride 2844.20.00.20 Other 2844.20.00.30
Imports of natural uranium metal and forms of natural uranium other than compounds:	
• Uranium Metal	2844.10.10.00
• Other	2844.10.50.00
Uranium depleted in U235 and its compounds; thorium and its compounds; alloys, dispersions (including cermets), ceramic products and mixtures containing uranium depleted in U235, thorium, or compounds of these products:	
• Uranium Compounds (Depleted)	Oxide 2844.30.20.10 Fluorides 2844.30.20.20 Other 2844.30.20.50
• Other (Depleted)	Uranium Metal 2844.30.50.10
Nuclear reactors; fuel elements (cartridges), non-irradiated, for nuclear reactors; machinery and apparatus for isotopic separation; parts thereof:	
• Fuel elements (cartridges), non-irradiated, and parts thereof	8401.30.00.00

Source: United States International Trade Commission and U.S. Department of Commerce, Bureau of Industry and Security.

In addition to the uranium products identified in Figure 1, this report examines the provision of three services in the nuclear fuel cycle: Conversion,[28] enrichment,[29] and fuel fabrication.[30] Transactions for these services are examined separately from transactions involving uranium hexafluoride (UF6), enriched uranium product (EUP) and finished fuel assemblies (fuel for nuclear power plants). The Department made this distinction because U.S. nuclear power operators, the end-consumer of most uranium products in the U.S., purchase services and finished products for UF6, EUP, and finished fuel assemblies.

A U.S. utility, for example, may opt to buy a specified amount of UF6, EUP, or finished fuel assemblies directly from a producer. Alternatively, it may directly contract for conversion, enrichment, or fuel fabrication services using material owned by the utility. These services are regularly procured both inside and outside the United States.

The Department determined that assessing U.S. utilities' procurement of UF6 or EUP through conversion, enrichment, and fuel fabrication services was critical to understanding the effects of imports of uranium products on U.S. national security. Information regarding conversion, enrichment, and fuel fabrication services was collected and incorporated into the investigation via the front-end uranium industry survey.

This report also examines the state of the U.S. nuclear power generation sector. The Department is aware that the principal customers of uranium are nuclear power reactor operators, thus examination of the U.S. nuclear power generation industry through a comprehensive Department survey was necessary to ensure a complete analysis of the effect of uranium imports on the national security. The Secretary's recommendations consider the interdependence of the U.S. uranium industry and the U.S. nuclear power generation sector.

V. Background on the U.S. Nuclear Industry

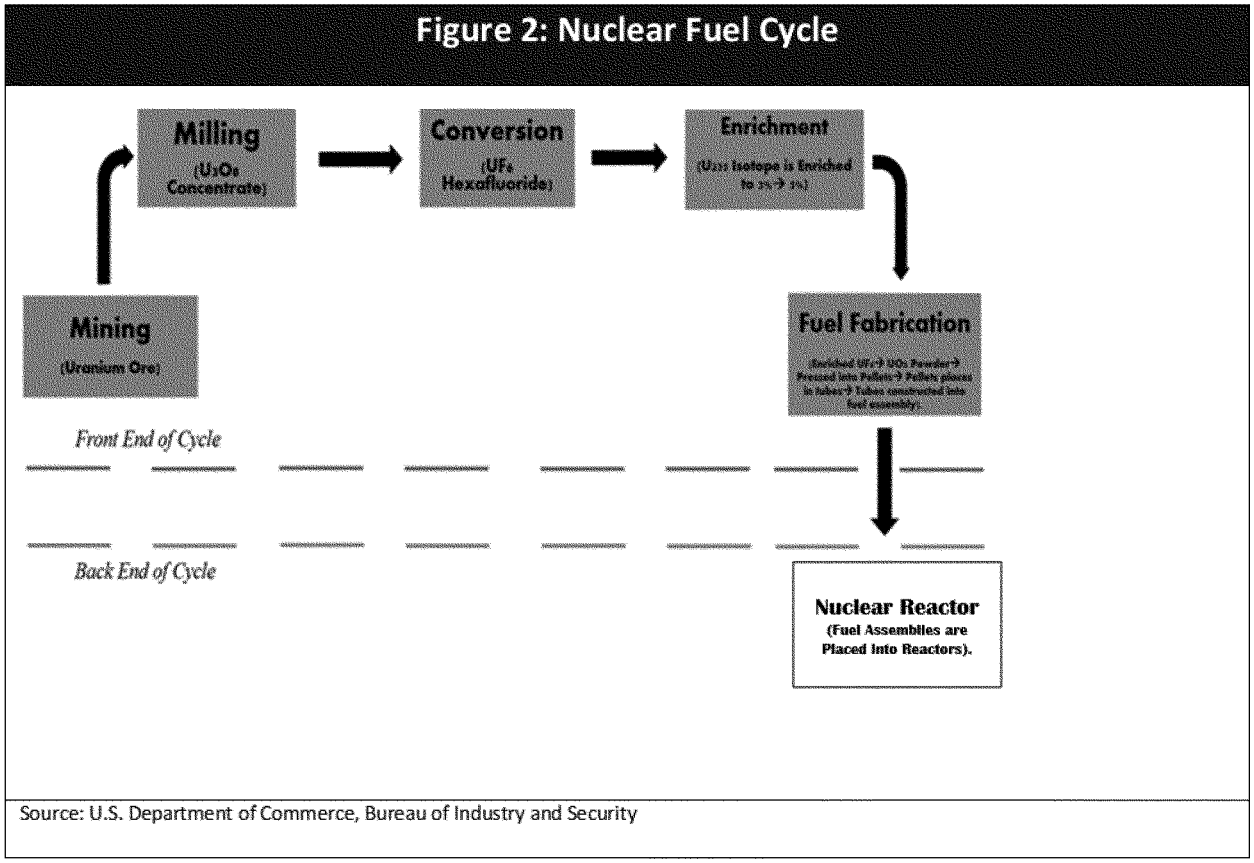
A. Summary of the U.S. Uranium Fuel Cycle

The processes that prepare uranium for use in nuclear power generation constitute the front-end of the nuclear fuel cycle. In the United States, these front-end processes consist of uranium mining, milling, conversion, enrichment, and nuclear fuel fabrication. The nuclear fuel cycle and its products at each stage are shown in Figure 2.

[28] Conversion is defined as the conversion of uranium concentrate (U3O8) to uranium hexafluoride (UF6).

[29] Enrichment is defined as the process that increases the concentration of Uranium-235 isotopes within a quantity of natural uranium.

[30] Fuel fabrication is defined as the process by which enriched uranium is converted to uranium dioxide powder that is then pressed into pellets and placed in fuel rods. Bundles of these fuel rods become fuel assemblies that are placed in nuclear reactors.



Uranium mining is the first step of the cycle. Several techniques are used for uranium mining including open pit, underground, and in-situ recovery (ISR). The ISR technique, used by all active U.S. uranium mining operations today, involves pumping a slightly acidic solution into ore bodies to dissolve uranium ore in preparation for extraction.[31]

The ore-bearing solution recovered from uranium mining is then transferred to a facility for processing into tri-uranium octoxide concentrate (U3O8), commonly referred to as uranium concentrate. For open pit and underground mines, uranium milling involves crushing ore and treating it with chemicals in order to produce U3O8.[32]

In 2018, all domestic uranium concentrate was produced by five ISR facilities located in Nebraska and Wyoming, and one milling operation located in Utah.[33] These facilities were the only operating uranium mines and mill in the U.S. in 2018, thus no uranium concentrate was produced by conventional underground or open-pit mines during the same year. Another five mines are currently licensed, but idled (*see* Figures 3 and 4).[34]

FIGURE 3: U.S. FUEL CYCLE FACILITIES—MINES

[In Situ Recovery]

Project name	Company name	Location	[TEXT REDACTED]
Crow Butte Operation	Cameco	Nebraska	[TEXT REDACTED].
Lost Creek Project	Ur-Energy (Lost Creek ISR LLC)	Wyoming	[TEXT REDACTED].
Smith Ranch-Highland Operation	Power Resource Inc., dba Cameco Resources	Wyoming	[TEXT REDACTED].
Ross CPP	Strata Energy Inc	Wyoming	[TEXT REDACTED].
Nichols Ranch ISR Project	Energy Fuels Resources Corp. (Uranerz Energy Corporation).	Wyoming	[TEXT REDACTED].
Willow Creek Project (Christenson Ranch & Irigaray).	Uranium One USA, Inc	Wyoming	[TEXT REDACTED].
Alta Mesa Project	Energy Fuels Resources Corp (Mestena Uranium LLC).	Texas	[TEXT REDACTED].
Hobson ISR Plant	South Texas Mining Venture	Texas	[TEXT REDACTED].
La Palangana	South Texas Mining Venture	Texas	[TEXT REDACTED].

[31] ''Nuclear Explained: The Nuclear Fuel Cycle.'' U.S. Energy Information Administration. *https://www.eia.gov/energyexplained/index.php?page=nuclear_fuel_cycle.*

[32] ''Conventional Uranium Mills.'' United States Nuclear Regulatory Commission. *https://www.nrc.gov/materials/uranium-recovery/extraction-methods/conventional-mills.html.*

[33] U.S. Energy Information Administration. *2017 Domestic Uranium Production Report.* (Washington, DC: 2017) *https://www.eia.gov/uranium/production/annual/pdf/dupr.pdf.*

[34] ''Locations of Uranium Recovery Facilities.'' United States Nuclear Regulatory Commission. *https://www.nrc.gov/info-finder/materials/uranium/.*

FIGURE 3: U.S. FUEL CYCLE FACILITIES—MINES—Continued

[In Situ Recovery]

Project name	Company name	Location	[TEXT REDACTED]
Goliad ISR Uranium Project	Uranium Energy Corp	Texas	[TEXT REDACTED].

Source: [TEXT REDACTED]; U.S. Energy Information Administration—Annual Domestic Uranium Production Report (2018). [TEXT REDACTED].

FIGURE 4: U.S. FUEL CYCLE FACILITIES—MILLS, 2018

Project name	Company name	Location	[TEXT REDACTED]
White Mesa Mill	EFR White Mesa LLC	Utah	[TEXT REDACTED].
Shootaring Canyon Uranium Mill	Anfield Resources	Utah	[TEXT REDACTED].
Sweetwater Uranium Project	Kennecott Uranium Company	Wyoming	[TEXT REDACTED].
Pinon Ridge Mill	Western Uranium/Pinon Ridge Resources Corporation.	Colorado	[TEXT REDACTED].
Sheep Mountain	Energy Fuels Wyoming Inc	Wyoming	[TEXT REDACTED].

Source: [TEXT REDACTED] U.S. Energy Information Administration—Annual Domestic Uranium Production Report (2018). [TEXT REDACTED].

U.S.-based mining and milling facilities have dramatically declined over recent years, falling from eighteen mines and four mills in 2009 to five operating mines and one operating mill in 2018. These facilities have shut down or idled for several reasons, including competition from subsidized foreign imports, low spot prices, as well as costs and delays associated with the U.S. permitting process.

Similarly, production of uranium concentrate (U308) in the United States has declined, dropping 95 percent from 43.7 million pounds in 1980 [35] to 1.97 million in 2018. Kazakhstan, Canada, and Australia were the top suppliers in 2017, producing roughly 46.8, 26.2, and 11.8 million pounds of uranium concentrate, respectively.[36]

The third step in the fuel cycle is conversion, where a gas is used to facilitate enrichment of the U–235 isotope in uranium concentrate into natural uranium (UF6). ConverDyn, the sole U.S. uranium conversion facility, is currently in standby/idled (*see* Figure 5).

FIGURE 5: U.S. FUEL CYCLE FACILITIES—CONVERSION, 2018

Project name	Company name	Location	Operating status
ConverDyn Metropolis Works	Honeywell Energy/ConverDyn	Metropolis, IL	Standby/Idle.

Source: [TEXT REDACTED] U.S. Nuclear Regulatory Commission.

ConverDyn began producing UF6 for commercial use in the 1960s and supplied commercial conversion services to the U.S. and global uranium market, competing against suppliers in Canada, Russia, France, and China.[37] However, it announced a suspension of operations in late 2017 related to ongoing challenges facing the nuclear fuel industry.[38] [TEXT REDACTED] Furthermore, the Russians, Chinese, and French bundle conversion services as part of their nuclear fuel sales. [TEXT REDACTED] [39]

Uranium enrichment, the fourth stage in the fuel cycle, produces material to be used in the operation of nuclear reactors. Natural uranium (UF6) consists of three distinct isotopes: U–234, U–235, and U–238. The enrichment process alters the isotopic makeup in order to increase the prevalence of the U–235 isotope. The U–235 isotope must be enriched so that fission, or splitting of the U–235 atoms, can occur to produce energy.[40] [41] Gaseous centrifuges are the industry standard for uranium enrichment into low-enriched uranium (LEU) or high-enriched uranium (HEU). LEU is used by commercial power reactors as fuel where the U–235 is enriched to between three and five percent. HEU is used in naval ships, submarines, nuclear weapons, and some research reactors,[42] [43] with enrichment at 20 percent.

[35] ''Annual Energy Review 2011.'' U.S. Energy Information Administration (Washington, DC: 2012). *https://www.eia.gov/totalenergy/data/annual/showtext.php?t=ptb0903.*

[36] ''Uranium Production Figures, 2008–2017.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/facts-and-figures/uranium-production-figures.aspx.*

[37] ''Conversion and Deconversion.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/nuclear-fuel-cycle/conversion-enrichment-and-fabrication/conversion-and-deconversion.aspx.*

[38] U.S. Energy Information Administration. *2017 Domestic Uranium Production Report.* (Washington, DC: 2017) *https://www.eia.gov/uranium/production/annual/pdf/dupr.pdf.*

[39] [TEXT REDACTED].

[40] ''Uranium Enrichment.'' United States Nuclear Regulatory Commission. *https://www.nrc.gov/materials/fuel-cycle-fac/ur-enrichment.html.*

[41] ''Uranium Enrichment.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/nuclear-fuel-cycle/conversion-enrichment-and-fabrication/uranium-enrichment.aspx.*

[42] ''Uranium Downblending.'' WISE Uranium Project. *http://www.wise-uranium.org/eudb.html.*

[43] Highly Enriched Uranium (HEU) is uranium with U–235 content of at least 20 percent. Naval reactors and weapons applications utilize HEU enriched to more than 90 percent U–235.

The United States first used gaseous diffusion uranium enrichment plants in the 1940s during the Second World War. Additional plants were built in the 1950s for defense needs and later opened for commercial enrichment use. These plants are located in Paducah, Kentucky and Piketon, Ohio, but both closed by 2013.[44] Today, URENCO USA (UUSA) is the only uranium enrichment company operating in the United States, serving the commercial power reactor market. UUSA is a subsidiary of URENCO Group, a consortium owned by the governments of the United Kingdom and the Netherlands, as well as two German utilities (*see* Figure 6). UUSA employs gas centrifuge enrichment at its Louisiana Energy Services (LES) plant in Eunice, New Mexico to produce LEU for nuclear reactor fuel.[45] Per the 1992 Washington Agreement governing the LES facility's construction and operation, the plant cannot be used to produce enriched uranium for U.S. defense purposes. However, in January 2019, DOE announced plans to reopen the Piketon facility to demonstrate a U.S.-origin centrifuge technology for production of High-Assay Low Enriched Uranium (HALEU) in support of advanced reactor development efforts.[46]

FIGURE 6: U.S. FUEL CYCLE FACILITIES—ENRICHMENT

Project name	Company name	Ownership	Enrichment type	Location	Operating status
Louisiana Energy Services (LES).	URENCO USA	United Kingdom, the Netherlands, Germany.	Gas Centrifuge	New Mexico	Operating.

Source: U.S. Nuclear Regulatory Commission.

The fifth and final step in the front-end nuclear fuel cycle is fuel fabrication, where enriched uranium is formed into pellets and then fabricated into fuel rods for fuel assemblies. Three active fuel fabrication plants in the U.S. are licensed to transform low-enriched uranium into fuel assemblies for commercial power reactors: Westinghouse, GE, and Framatome (*see* Figure 7).

Naval reactors require HEU fuel and their fuel assemblies come from a different supply base. All uranium used in the manufacture of naval fuel assemblies is from the Department of Energy's stockpile and is not currently purchased on the commercial market. The naval fuel is manufactured by BWX Technologies (BWXT) at its Nuclear Fuel Services (NFS) facility in Tennessee. Additionally, BWXT downblends high-enriched uranium (HEU) to produce low-enriched uranium (LEU), which is needed to produce the tritium required for nuclear weapons.[47]

FIGURE 7: U.S. FUEL CYCLE FACILITIES—FUEL FABRICATION, 2018

Company name	Ownership	NRC category	Location	Operating status
BWXT Nuclear Operations Group.	United States	Category 1	Virginia	Operating.
Nuclear Fuel Services, Inc	United States	Category 1	Tennessee	Operating.
Framatome, Inc	France	Category 3	Washington	Operating.
Global Nuclear Fuel—Americas LLC (General Electric).	United States	Category 3	North Carolina	Operating.
Westinghouse	United States	Category 3	South Carolina	Operating.

Category 1: High Strategic Significance.
Category 3: Low Strategic Significance (commercial services).
Source: U.S. Nuclear Regulatory Commission.

B. Summary of U.S. Nuclear Power Generation Industry

The first U.S. commercial nuclear reactor came online in 1958, and most active U.S. reactors were built between 1967 and 1990. Originally certified for 40 years of operation, the lifespans of 85 reactors have been extended by the Nuclear Regulatory Commission (NRC) for an additional 20 years. These certifications followed assessments confirming that they were safe to continue operating well after the end of their original design life.

As of October 2018, 98 reactors were located at 58 different facilities in 28 states across the country[48] (*see* Figure 8). The two main commercial reactor designs used for power generation are pressurized-water reactors (PWR) and boiling-water reactors (BWR), with 65 and 33 operating in the U.S., respectively. These reactors have varying designs, dimensions, and numbers of fuel rods in each fuel assembly based on the six commercial power reactor manufacturers in the United States: Allis-Chalmers, Babcock & Wilcox, Combustion Engineering, General Atomics, General Electric, and Westinghouse.[49]

[44] "Nuclear Power in the USA." World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-t-z/usa-nuclear-power.aspx.*

[45] "Uranium Enrichment." United States Nuclear Regulatory Commission. *https://www.nrc.gov/materials/fuel-cycle-fac/ur-enrichment.html.*

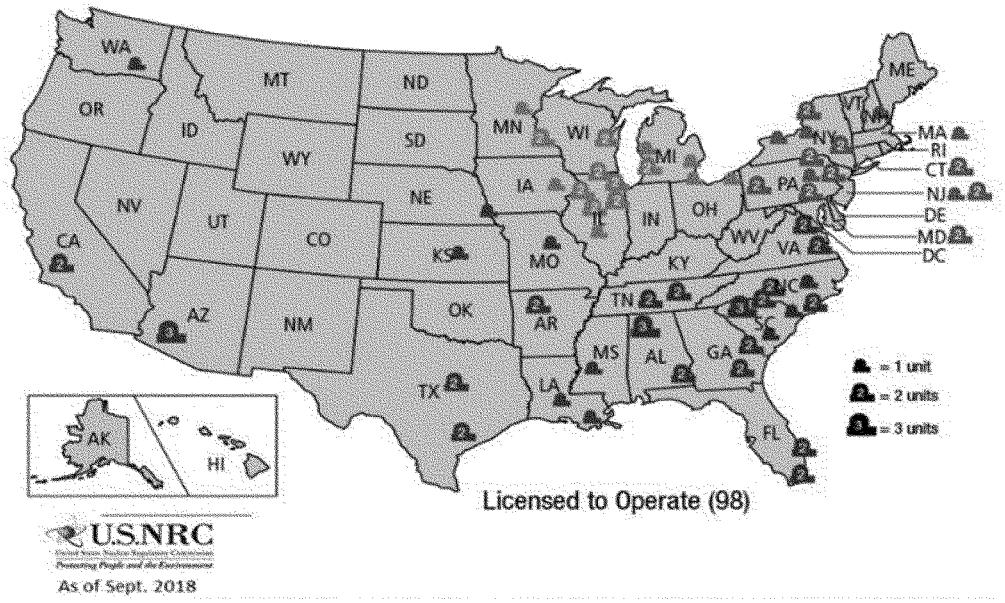
[46] "DOE Plans $115M Investment in Uranium Enrichment Project." *U.S. News & World Report,* January 8, 2019. *https://www.usnews.com/news/best-states/ohio/articles/2019-01-08/doe-plans-115m-investment-in-uranium-enrichment-project.*

[47] "Nuclear Fuel Fabrication—Current Issues (USA)." WISE Uranium Project.

[48] "Monthly Energy Review March 2019." U.S. Energy Information Administration. *https://www.eia.gov/totalenergy/data/monthly/pdf/sec7_5.pdf.*

[49] "Fuel Fabrication." United States Nuclear Regulatory Commission. *https://www.nrc.gov/materials/fuel-cycle-fac/fuel-fab.html.*

Figure 8: U.S. Operating Commercial Power Reactors, 2018



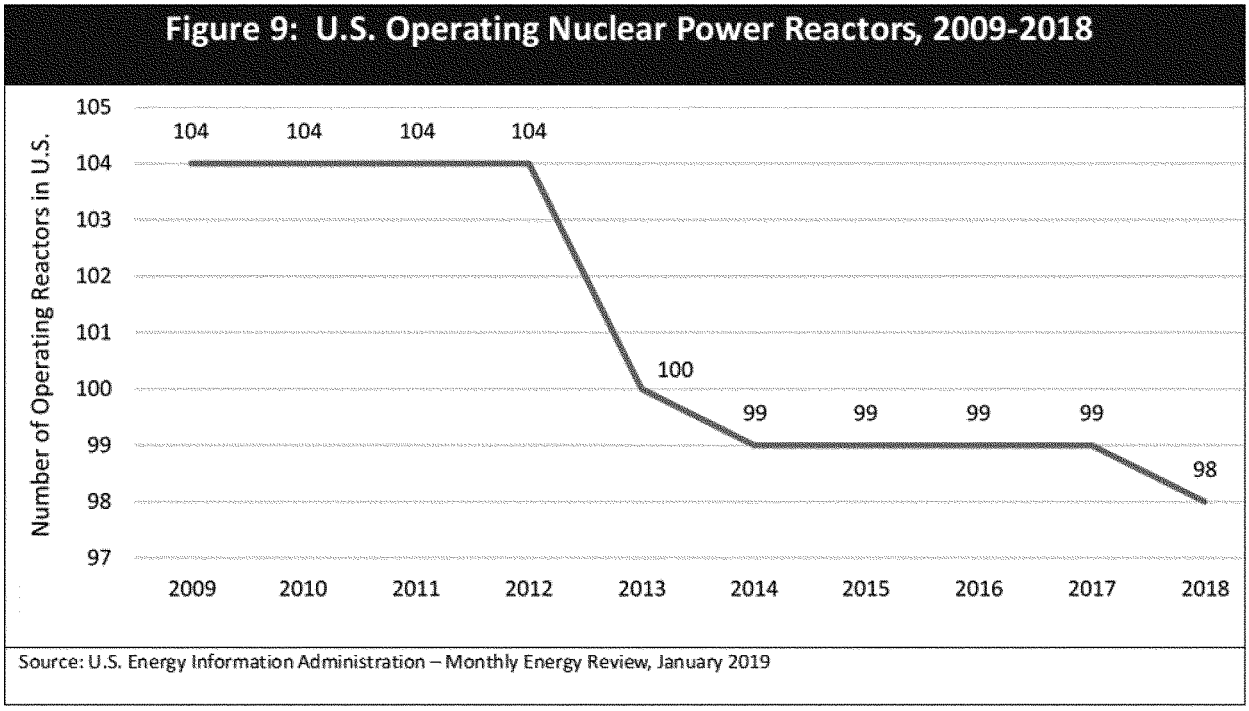
Source: U.S. Nuclear Regulatory Commission

These reactors are important to produce steady-state baseload power to the U.S., in contrast to hydro, solar, and wind, which have fluctuating generating capabilities.[50] [51] Despite providing a significant portion of the nation's electricity (more than 19 percent), a number of U.S. utilities have prematurely retired their nuclear power reactors due to cost pressures resulting from distortions in wholesale electricity market pricing mechanisms, subsidized renewable energy, and lower natural gas prices. Since 2013, U.S. electric utilities have permanently closed six nuclear power plants. Another eight reactors are slated to be retired between 2019 and 2025.[52] However, two new reactors are scheduled to come online by 2022. The domestic uranium industry is challenged by this shrinking customer demand for their product in the United States (*see* Figures 9 and 10).

[50] ''Frequently Asked Questions.'' U.S. Energy Information Administration. *https://www.eia.gov/tools/faqs/faq.php?id=207&t=3.*

[51] ''Nuclear Power in the USA.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-t-z/usa-nuclear-power.aspx.*

[52] U.S. Energy Information Administration. ''America's oldest operating nuclear power plant to retire on Monday'' (September 14, 2018), *https://www.eia.gov/todayinenergy/detail.php?id=37055.*



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Source: [TEXT REDACTED].
[TEXT REDACTED].

The majority of the plants shut down due to cost-driven factors, including competition from alternative generation sources such as natural gas, solar, and wind, as well as additional capital expenditures needed to meet NRC regulatory requirements. [TEXT REDACTED]

Only one new reactor has been completed in the United States since 1996—Tennessee Valley Authority's Watts Bar 2 plant, which began operating in 2016. Construction started on two commercial PWR reactors in Georgia in 2013 and those are scheduled to begin operation in 2021. In South Carolina, construction of two commercial reactors began in 2013, but cost overruns caused the projects to be abandoned in 2017.[53] [54] While the U.S. nuclear power industry is declining, global demand for nuclear power plants is rising with no less than 50 new reactors under construction in 15 countries. A majority of the new builds are in Russia, China, India, the United Arab Emirates, and South Korea.[55]

VI. Global Uranium Market Conditions

A. Summary of the Global Uranium Market

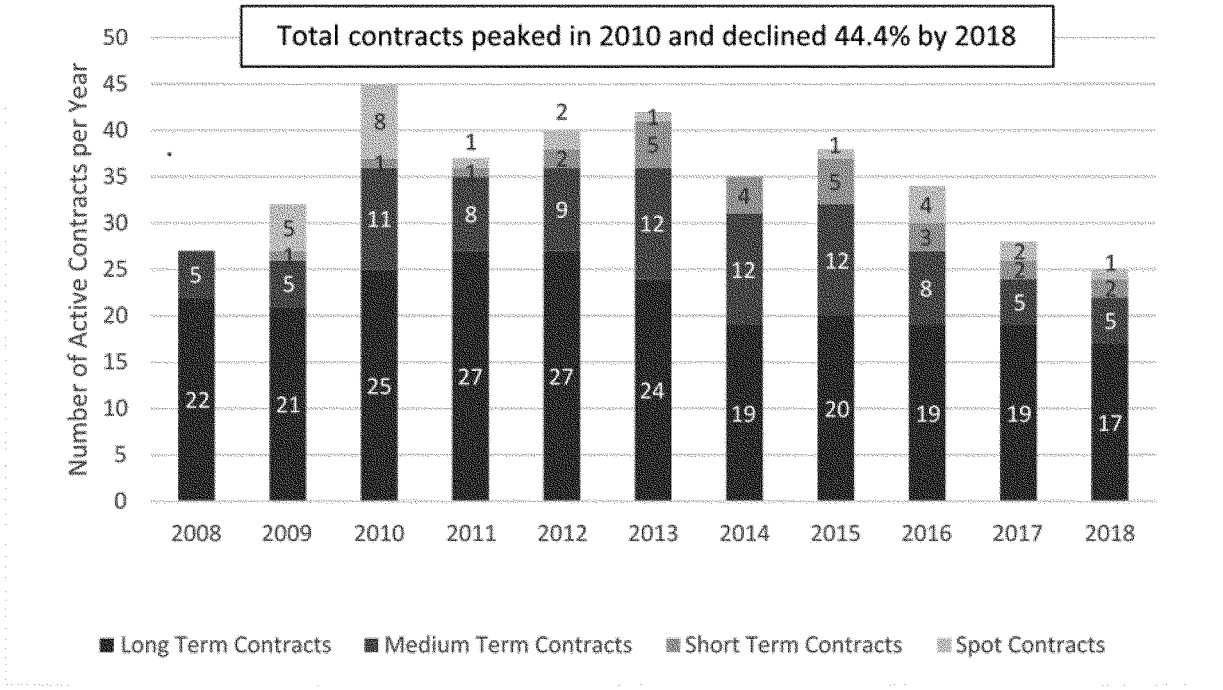
Uranium, in various forms (''uranium''), is a globally-traded commodity supplied primarily through privately negotiated contracts with varying durations. Short-term contracts usually span less than two years, mid-term contracts run between two to five years, and long-term contracts can be in force for five years or more. Additionally, uranium can be bought on ''spot,'' which are contracts with a one-time uranium delivery (usually) for the entire contract, where the delivery occurs within one year of contract execution. The spot market can be lower or higher than the contract market. Since 2011, the number of spot, mid-term, and long-term contracts for all front-end industry participants has varied (*see* Figure 11). Of note, long-term contracts have declined from 35 to just 19, and no short-term contracts were reported.

[53] ''Nuclear Power in the USA.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-t-z/usa-nuclear-power.aspx.*

[54] Stelloh, Tim. ''Construction Halted at South Carolina Nuclear Power Plant.'' *NBC News,* July 31, 2017. *https://www.nbcnews.com/news/us-news/construction-halted-south-carolina-nuclear-power-reactors-n788331.*

[55] ''Plans for New Reactors Worldwide.'' World Nuclear. *http://www.world-nuclear.org/information-library/current-and-future-generation/plans-for-new-reactors-worldwide.aspx.*

Figure 11: Total Active Front-End Uranium Contracts by Contract Term



Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab9a

12 respondents

The spot market price of a pound of uranium averaged only $28.27 in the last three months of 2018, and dropped even further to $25.75 in April 2019. This is a 74 percent reduction since the recent price high of $99.24 per pound in 2007.

According to Department survey respondents, the main factor causing the current low spot market price of uranium is global excess uranium supply, much of which is attributed to continued production of uranium from state-owned enterprises in the aftermath of the Fukushima incident. Low spot prices have significantly impacted the viability of U.S. uranium producers. Mining companies operating in the U.S. have been forced to idle operations due to low spot prices, and since 2009, four companies have closed 10 mines with the intention to permanently halt operations.

Additionally, the U.S. has approximately 1.28 million metric tons of uranium in prognosticated uranium resources (the largest reserves in the world [56]), much of which has not been developed specifically due to low spot prices (*see* Figure 12).

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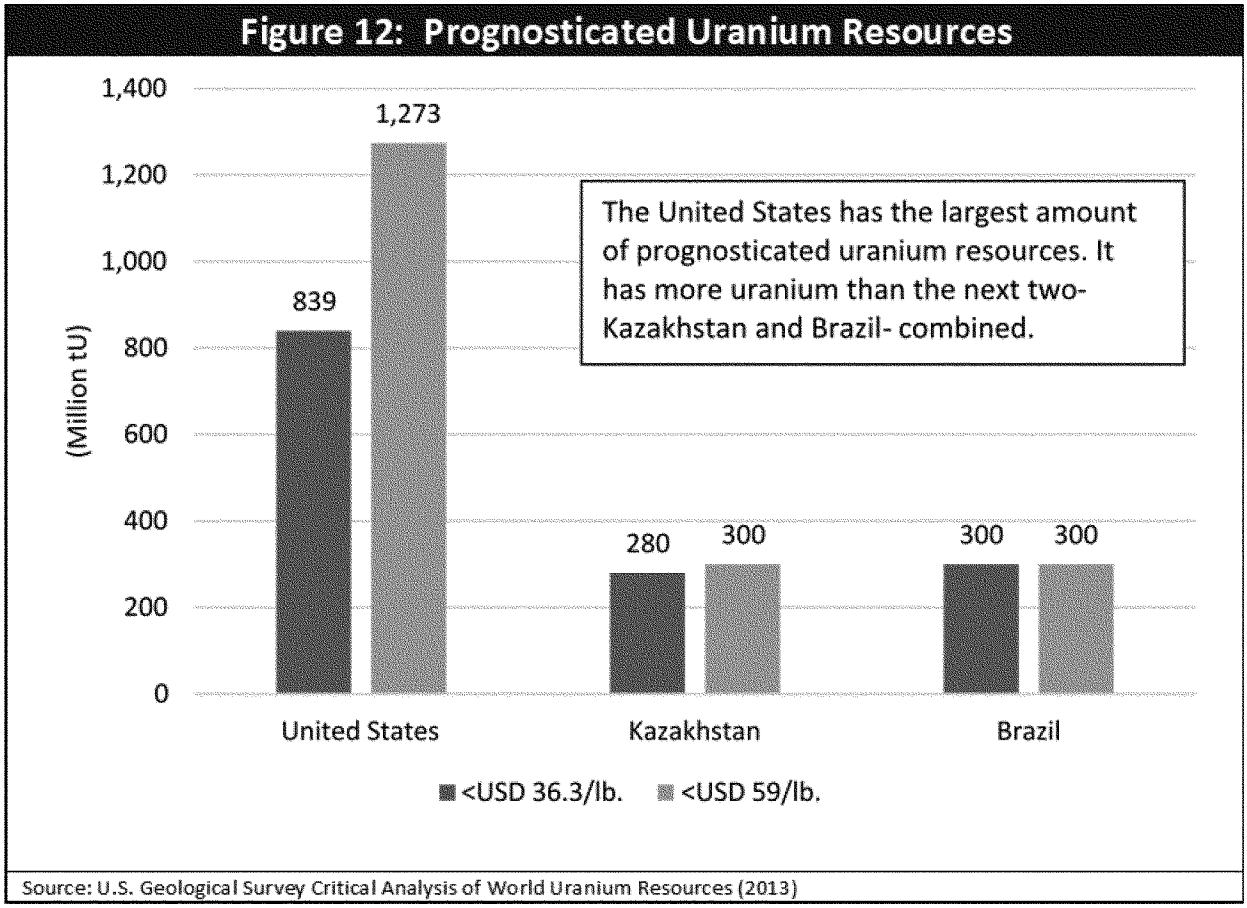
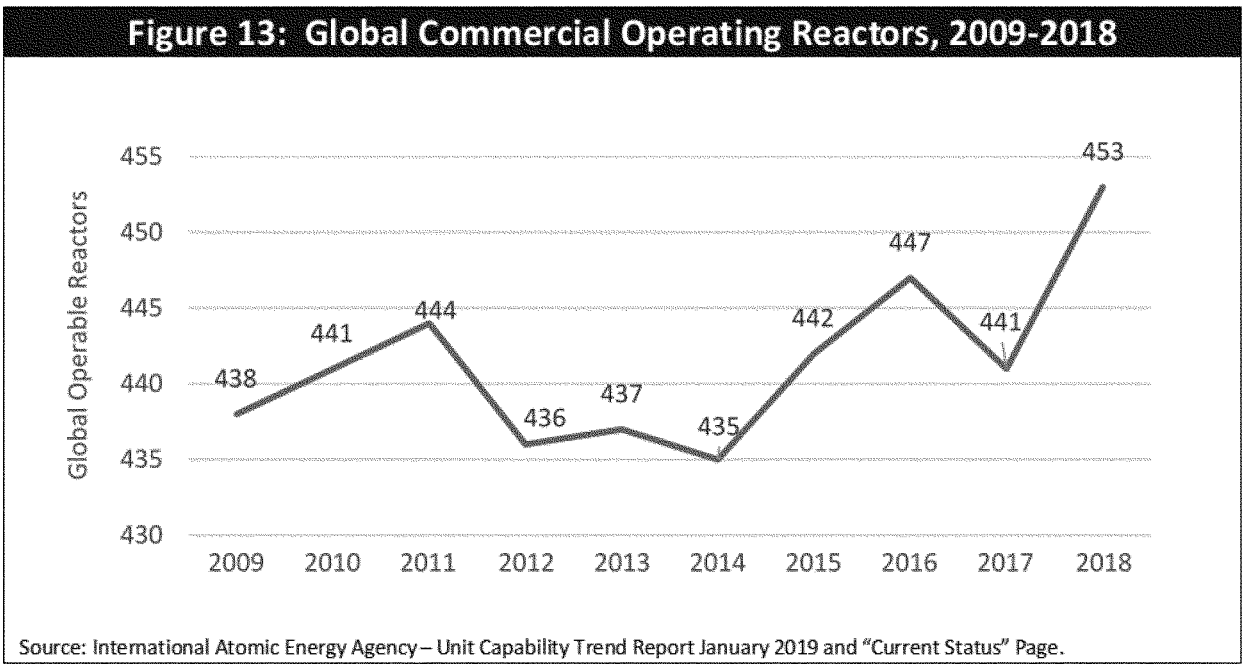
[56] Susan Hall and Margaret Coleman, U.S. Geological Survey, *Critical Analysis of World Uranium Resources,* (2013) pp. 26–27.

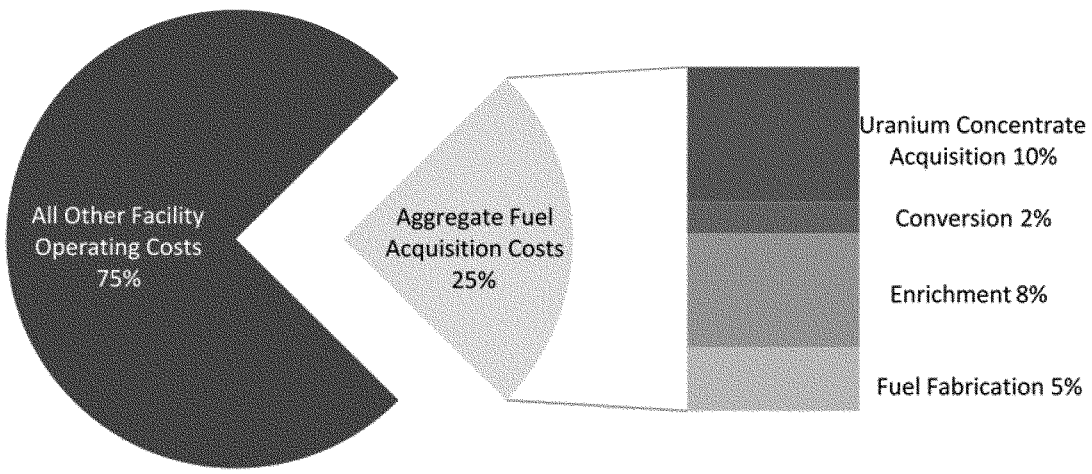


Nuclear fuel prices are, however, impacted by more than just the uranium spot market price. On the supply side, uranium prices are affected by mine closures and the release of existing inventory for sale. On the demand side, price is impacted by new reactor startups and reactor closures (*see* Figure 13).



Additionally, converters, enrichers, and fuel fabricators experience specific market pressures, resulting in uranium products that have slightly different price considerations. Department survey data indicates that, on average, aggregate fuel acquisition accounts for 25 percent of total facility operating costs. When looking at fuel acquisition as a percentage of a nuclear power utilities' total facility operating costs, the contribution of each stage of the front-end nuclear fuel cycle is relatively small: Mining/milling and uranium concentrate acquisition (10 percent), enrichment (8 percent), fuel fabrication (5 percent), and conversion (2 percent) (*see* Figure 14).

Figure 14: Fuel Acquisition as a Percentage of Total Facility Operating Costs



Source: U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power Operator Survey, Q3C *22 Respondents*

B. Uranium Transactions: Book Transfers and Flag Swaps

Unlike many commodities, exchanges of uranium between suppliers and customers often take place without physical movement of material. This occurs through book transfers and flag swaps.

Book Transfer

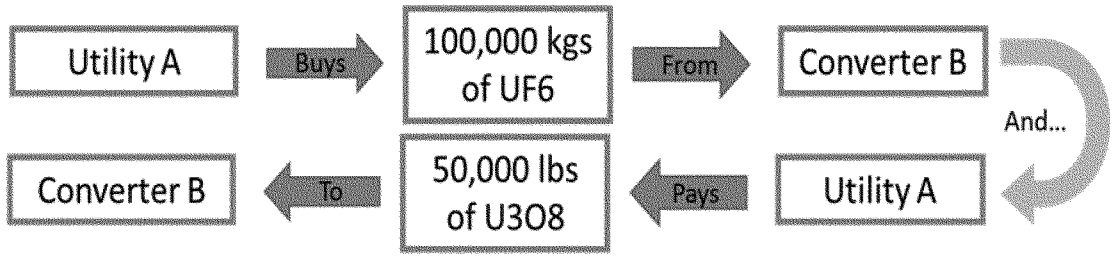
For the purposes of this investigation, a book transfer is defined as a ''change of ownership of two quantities of material with all other characteristics of the material being unchanged.'' [57] Book transfers are used to exchange material between two customers at a third-party producer without having to physically ship or otherwise move material (*see* Figure 15).

[57] *Swaps in the International Fuel Market,* 7. World Nuclear Association. *http://www.world-nuclear.org/uploadedFiles/org/WNA/Publications/Working_Group_Reports/swaps-report-2015.pdf, 7.*

Figure 15: Example of Book Transfer		
	Utility A	**Mine B**
Before	**Where (Account Location)**: Converter C, USA **What (Contract)**: Buy 100,000 pounds of U3O8 from Mine B. **Where (U3O8 Origin):** Not yet purchased	**Where (Account Location)**: Converter C, USA **What (Contract)**: Provide 100,000 pounds of U3O8 to Utility A. **Where (U3O8 Origin):** Country D
What Happens: Mine B already has 100,000 pounds of U3O8 in Converter C's Account Mine B Transfers U3O8 at Converter C to Utility A →		
After	**Account Location**: Converter C, USA **Contract**: Buy 100,000 pounds of U3O8 from Mine B. **U3O8 Origin:** Country D	**Account Location**: Converter C, USA **Contract**: *Transfer 100,000 pounds of U3O8 at Converter C to Utility A's account* **U3O8 Origin:** Country D
NOTE: In this example, 100,000 pounds of U308 has changed ownership from Mine B to Utility A, but retains its origin from Country D.		
Source: U.S. Department of Commerce, Bureau of Industry and Security		

Book transfers also can be used to convey payment for conversion or enrichment services (*see* Figure 16).[58]

Figure 16: Payment for Conversion Services via Book Transfer



Source: U.S. Department of Commerce, Bureau of Industry and Security

Flag Swap

In certain cases, utilities and uranium industry producers may find it necessary to conduct ''obligation swaps'' of material, a practice commonly known as ''flag swapping.''[59] In the uranium industry, obligations are defined as conditions assigned by a particular country's government to a specific set of nuclear material. These conditions control the use of nuclear material, including uranium, and may restrict where it is shipped. For example, if such material has a United States obligation, the material can only be used in accordance with conditions established by the United States government.[60]

Depending on the parties involved in the uranium exchange, it is possible for a given quantity and type of uranium to acquire multiple obligations. If material is mined in Canada, converted in the United States, enriched in Germany,

[58] Ibid.

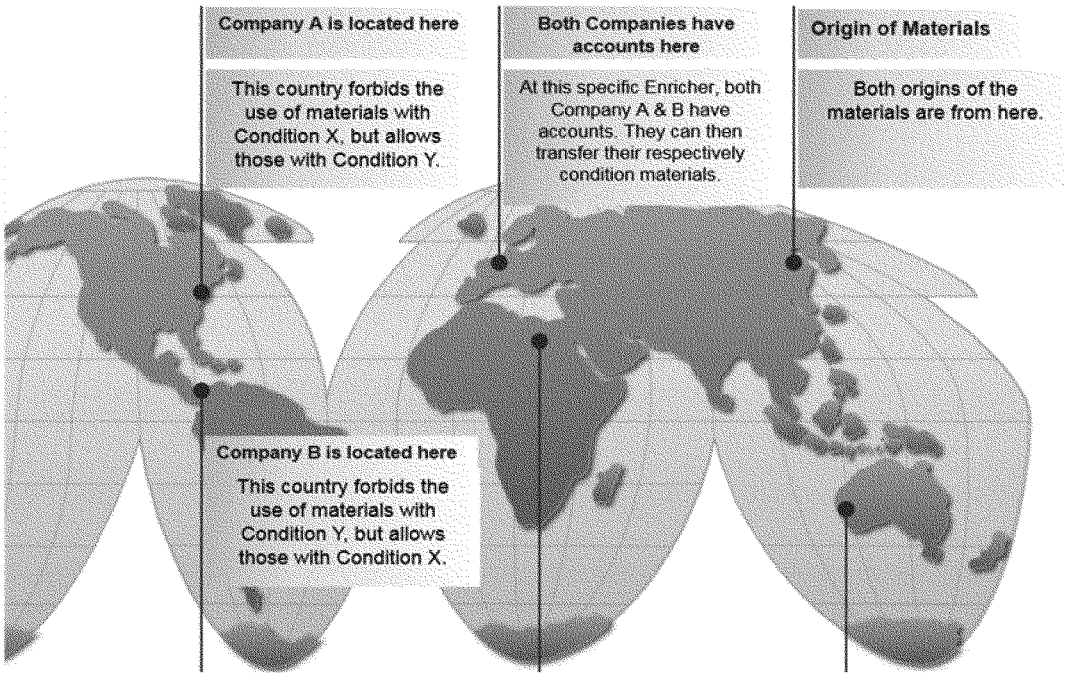
[59] ''Swaps in the International Fuel Market.'' World Nuclear Association. (2015). *http://www.world-nuclear.org/uploadedFiles/org/WNA/Publications/Working_Group_Reports/swaps-report-2015.pdf*

[60] In this example, the United States obligations associated with material are established in U.S. peaceful nuclear cooperation agreements, also known as 123 agreements. Section 123 of the Atomic Energy Act of 1954 generally requires the entry into force of a peaceful nuclear cooperation agreement prior to significant exports of U.S. nuclear material or equipment. As of 2019, the United States has in force approximately 23 of these agreements with foreign partners. Congressional Research Service. *Nuclear Cooperation with Other Countries: A Primer,* 1. (Washington, DC: 2019). https://crsreports.congress.gov/product/pdf/RS/RS22937

and fabricated into nuclear fuel in Japan, then the uranium would then acquire obligations from Canada, the United States, the European Atomic Energy Community (EURATOM), and Japan. The uranium can only be used in accordance with regulations imposed by the above countries and EURATOM. Customers and producers engage in obligation swaps to ease administrative burdens on the maintenance of material. By exchanging in obligation swaps, customers and producers can minimize the number of obligations that must be adhered to for the tracking and ultimate use of uranium materials (*see* Figures 17 and 18).

Note that the exchange of obligations does not change the origin. Although origin swaps are usually not permitted by regulatory authorities, it is possible to *de facto* origin swap through a change of obligation and ownership. These combination obligation/ownership swaps have in the past been used to circumvent uranium import restrictions, as previously encountered with South African and Soviet-origin uranium in the late 1980s.[61]

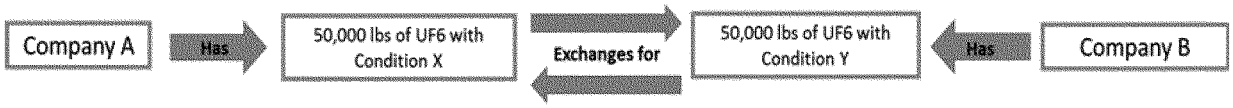
Figure 17: Obligation Swap, Example 1



NOTE: Company A has 50,000 pounds of UF6 with Obligation X. Company B has 50,000 pounds of UF6 with Obligation Y. Both quantities of UF6 have Origin P.

Source: U.S. Department of Commerce, Bureau of Industry and Security

Figure 18: Obligation Swap, Example 2



Source: U.S. Department of Commerce, Bureau of Industry and Security

Book transfers and flag swaps are also advantageous because of the specialized nature of the nuclear fuel cycle. Nuclear fuel facilities are concentrated in only a few countries: five nations have uranium conversion facilities (the United States, Canada, China, France, and Russia) and eight enrichment facilities[62] (the aforementioned countries as well as Germany, the United Kingdom, and the Netherlands). Consequently, book transfer and flag swaps ensure that converters and enrichers can quickly process customer orders.

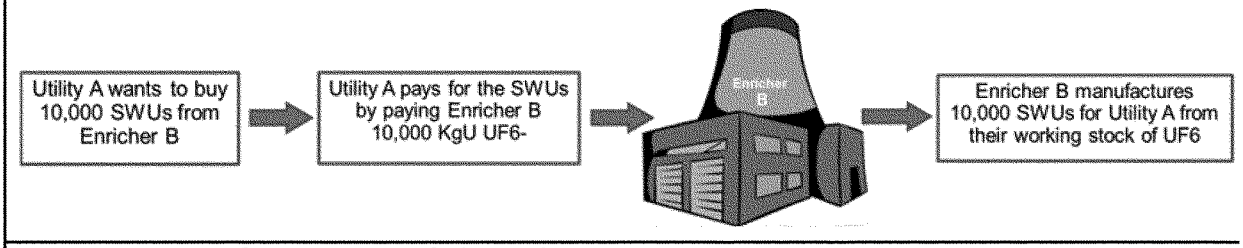
Furthermore, the nature of the uranium industry's manufacturing processes mean that an individual

[61] In these cases, South African and Soviet producers used third-party brokers to facilitate origin swaps that would circumvent restrictions on imports of these materials. DOC 1989 investigation, also, Written Question by Mr. Paul Saes (V) to the Commission of the European Communities, 26 February 1990, *http://publications.europa.eu/resource/cellar/a6838643-4b6d-4f39-aebb-d538ff795091.0004.01/DOC_1.*

[62] Ibid.

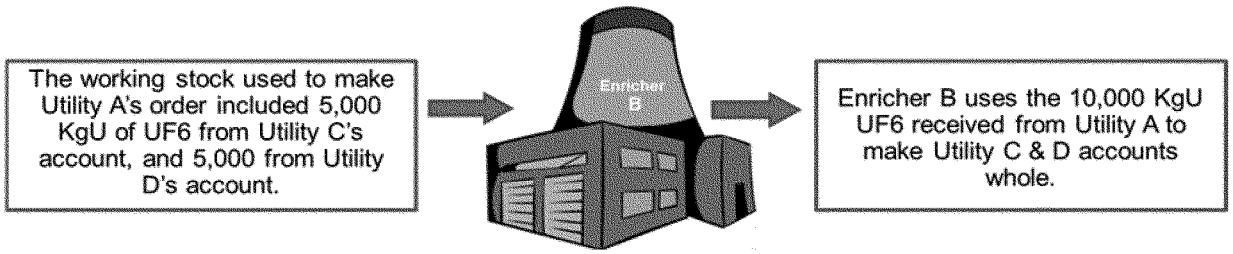
company's inventories of material are not kept separately at their facilities. Instead, materials are stored at converters, enrichers, and fuel fabricators (*see* Figures 19 and 20).[63] At these facilities, customers are assigned a particular share of the facility's product proportional to the amount specified in their contract. In this sense, uranium industry transactions function in the same way as banking transactions. An individual bank customer withdrawing $100 from an ATM does not receive the same physical $100 that he or she deposited at an earlier point. Similarly, a utility customer does not receive an end product—whether UF6, SWU, or fabricated fuel assemblies—to be the source material that the utility supplied to the producer.

Figure 19: Reconciliation of Book Transfer Accounts, Example 1



Source: U.S. Department of Commerce, Bureau of Industry and Security

Figure 20: Reconciliation of Book Transfer Accounts, Example 2



Source: U.S. Department of Commerce, Bureau of Industry and Security

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The Department incorporated its understanding of book transfers and flag swaps to its survey instrument and interpretation of responses. The Department is particularly cognizant of the reality that many imports of uranium into the United States do not necessarily occur through physical transportation of materials into the country. As described above, U.S. uranium producers and U.S. utilities can acquire and exchange materials without them ever entering the country. Consequently, the Department accounts for these types of transfers in assessing the overall impact of imported uranium on the national security.

C. The Effect of the Fukushima Daiichi Incident on U.S. and Global Uranium Demand

Reduction in global uranium demand in recent years can be traced to several factors including the impacts of Japan's Tōhoku earthquake and the subsequent meltdown at the Fukushima Daiichi Nuclear Power Plant. This event profoundly affected the economics of the nuclear industry by reducing global demand for uranium. Some governments in the developed world reacted to the Fukushima incident by closing existing reactors and cancelling plans for new construction. Japan cancelled plans for 14 new reactors and shut down all 50 operable reactors by 2012 to reassess safety standards. Since then, only nine have restarted.[64] Germany decided to shut down all 17 of its reactors by 2022[65] and France announced plans to shut down 14 reactors by 2035.[66] As of 2019, Germany has closed 10 reactors, while France has not yet closed any.[67] Consequently, the global uranium market was flooded with uranium products after a significant reduction in nuclear power plants operating worldwide.

[63] Ibid.

[64] ''Nuclear Power in Japan.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-g-n/japan-nuclear-power.aspx.*

[65] Annika Breidthart, ''German government wants nuclear exit by 2022 at latest'', Reuters (May 30, 2011), *https://uk.reuters.com/article/idINIndia-57371820110530.*

[66] ''Nuclear Power in France.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-a-f/france.aspx.*

[67] ''Nuclear Power in Germany.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-g-n/germany.aspx.*

Twelve projects primed for construction in the United States, encompassing seventeen new nuclear reactors, were canceled/postponed following the post-Fukushima upgrades mandated by the Nuclear Regulatory Commission. The new NRC requirements, coupled with the resurgence in public opposition to nuclear power, have been deterrents to future construction. Intense competition from other energy generation methods, paired difficulties in securing financing, also increased costs of new construction (*see* Figure 21). The number of active nuclear power plants worldwide reached a low in 2014 of 435 operating reactors. Although the number of reactors has since increased to 453 in 2018, the oversupply of uranium that remains in the market has continued to depress global prices.

FIGURE 21: CANCELLED NUCLEAR PROJECTS SINCE 2009

Facility name	Location	Projected generation capacity (MW)	Date of cancellation	Reason for cancellation
Bellefonte 2–4	Hollywood, AL	3,435	August 2009	Unfavorable market conditions.
Victoria County Station	Victoria, TX	3,070	August 2012	Unfavorable market conditions, competition from natural gas.
Shearon Harris 2–3	New Hill, NC	2,017	May 2013	Regulatory concerns, unfavorable market conditions.
Comanche Peak 3–4	Glen Rose, TX	3,400	November 2013.	Delay in reactor design review.
Nine Mile Point 3	Scriba, NY	1,600	November 2013.	Unfavorable market conditions.
Calvert Cliffs 3	Lusby, MD	1,600	July 2015	Unfavorable market conditions, inability to secure financing.
Callaway 2	Steedman, MO	1,600	August 2015	Regulatory concerns, unfavorable market conditions.
Grand Gulf 3	Port Gibson, MS	1,520	September 2015.	Unfavorable market conditions.
River Bend 3	St. Francisville, LA	1,520	December 2015.	Unfavorable market conditions.
Bell Bend 1	Salem Twp., PA	1,600	August 2016	Suspension of reactor design certification.
Bellefonte 1	Hollywood, AL	1,100	May 2016	Unfavorable market conditions.
V.C. Sumner 2–3	Jenkinsville, SC	2,500	July 2017	Unfavorable market conditions, cost overruns.
Levy County Nuclear Power Plant	Levy County, FL	2,234	August 2017	Unfavorable market conditions, public opposition.

Source: U.S. Nuclear Regulatory Commission.

D. The Effect of State-Owned Enterprises on Global Uranium Supply

The business practices of state-owned enterprises (SOEs) cause significant challenges for U.S. uranium producers. SOEs are insulated from market pressures in which the U.S. and other market producers, namely those in Australia and Canada, must contend. Specifically, a steep drop in uranium spot market prices can adversely affect miners' ability to cover their operating costs. In contrast, SOEs often produce uranium regardless of price because state support enables SOEs to make business decisions insensitive to market conditions. For example, although global uranium production declined by six percent between 2012 and 2014, Kazakhstan's production of uranium increased by seven percent over the same time period.[68] In Kazakhstan's case, state support includes state-financed exploration services[69] and employee training, as well as currency devaluation to artificially depress prices of all exports, including uranium.[70] State-owned suppliers dominate the list of leading global uranium producers (*see* Figure 22).

FIGURE 22: LEADING GLOBAL URANIUM PRODUCERS

Company	Ownership	Uranium production (in tons of MT)	Global market share (%)
KazAtomProm	*Kazakhstan*	*12,093*	*20*
Cameco	Private	9,155	15
Orano	*France*	*8,031*	*13*
Uranium One	*Russia*	*5,102*	*9*
CNNC & CGN	*China*	*3,897*	*7*
ARMZ	*Russia*	*2,917*	*5*
Rio Tinto	Private	2,558	4
Navoi	*Uzbekistan*	*2,404*	*4*
BHP Billiton	Private	2,381	4

[68] IAEA Red Book, 102, 2016.

[69] Global Business Reports, ''Kazakhstan's mining industry: Steppe by Steppe'', *Engineering and Mining Journal* (September 2015), p. 83, *https://www.gbreports.com/wp-content/uploads/2015/09/Kazakhstan_Mining2015.pdf.*

[70] In August 20, 2015 the National Bank of Kazakhstan allowed the national currency—the tenge—to float freely. Immediately, the tenge fell in value. Before the transition, the tenge had limited ability to move within a range determined by the national bank, resting at 185.7 KZT per USD. With the introduction of a free floating exchange rate, the currency has been consistently devaluing and resides at 380.1 KZT per USD (Department of Treasury). The switch to a free floating exchange rate was motivated in part to an effort to prop-up Kazak oil and resource sectors. The transition has successfully boosted growth in mining and resource markets. For more, consult Andrew E. Kramer, ''Kazakhstan's Currency Plunges'', *New York Times* (August 20, 2015) *https://www.nytimes.com/2015/08/21/business/international/kazakhstans-currency-plunges.html.*

FIGURE 22: LEADING GLOBAL URANIUM PRODUCERS—Continued

Company	Ownership	Uranium production (in tons of MT)	Global market share (%)
Energy Asia	Private	2,218	4
General Atomics/Quasar	Private	1,556	3
Sopamin	*Niger*	*1,118*	*2*
Paladin	Private	970	2

Italicized = State Ownership.
Not Italicized = Private Ownership.
Source: World Nuclear Association—World Uranium Mining Production, 2017.

The leading global uranium producers account for about 92 percent of current world uranium production. Of these, SOEs in the former Soviet Union and China control about 45 percent of the global market. These companies are insulated from market and regulatory pressures experienced by market producers, placing U.S. uranium mines at a distinct disadvantage.

Uranium-related SOEs, however, have broader roles than sales of uranium products. Many countries leverage their SOEs' integration of the nuclear fuel cycle and nuclear power generation to further geopolitical ambitions. Rosatom, a Russian state-owned enterprise that participates in every step of the nuclear fuel cycle, including power generation, uses this leverage. With virtually complete control over the Russian nuclear industry, Rosatom can offer prices for nuclear plant construction and fuel services that are significantly below that of market-based suppliers. Generous financing packages, usually consisting of low-cost loans underwritten by the Russian government, also incentivize deals with Rosatom.[71] China emulates Rosatom's model of pairing subsidized nuclear construction with state-supported financing, as seen with its construction of reactors in Pakistan and Romania. Summaries of individual countries' non-market economy nuclear activities are discussed more in Appendix I.

Uranium-related SOEs also have a deleterious impact on U.S. nonproliferation objectives. U.S. exports of nuclear technologies and supplies, including uranium products, are generally governed by Section 123 agreements.[72] These agreements, which include peaceful use restrictions and other nonproliferation requirements, ensure that the U.S. nuclear industry can play a role in the global nuclear fuels trade without contributing to nuclear weapons development. However, if the U.S. uranium industry cannot compete with SOEs, particularly Russia and China, the U.S. contribution to global nuclear nonproliferation regimes will substantially diminish. As former Secretary of Energy Enest Moniz remarked in July 2017:

> ''A world in which Russia and China come to have dominant positions in the global nuclear supply chain will almost certainly see a weakening of requirements, just as nuclear technology and materials spread to many countries.''[73]

U.S. utilities contract with uranium-related SOEs in Russia, Kazakhstan, Uzbekistan, and China primarily because of concerns with price and diversity of supply. These utilities believe that with the limited number of worldwide uranium producers, particularly in the conversion and enrichment stages, any additional competition is welcome. Most of the 24 utility respondents indicated that price and reliability of delivery considerations were the chief drivers of their fuel procurement policies; only [TEXT REDACTED] alluded to geopolitical considerations as a significant factor. Domestic utilities' desire to cut costs includes support for increased market penetration by China. [TEXT REDACTED]

Utilities' emphasis on diversity of supply also underpins their rationale for purchasing Russian uranium. [TEXT REDACTED][74] Several utilities suggested that if current restrictions on Russian imports were eliminated, they would purchase more Russian material.[75]

France

Respondents have also raised concerns about the activities of French state-owned enterprises. There are two principal French companies participating in the nuclear fuel cycle: Orano and Framatome. Orano, previously a part of Areva SA, is minority-owned by the French state and has direct ownership of uranium mines in Niger, Kazakhstan, and Canada. It also owns and operates all uranium enrichment and conversion facilities in France. Framatome, which is majority owned by the French government's electric utility *Électricité de France,* operates fuel fabrication and reactor construction businesses.

U.S. producers acknowledge that state support gives Orano and Framatome a competitive edge over U.S. and other European firms. [TEXT REDACTED] expressed concerns that, if U.S. anti-dumping duties on French enriched uranium were lifted, Orano's state backing would allow it to sell to utilities below-market cost.

The U.S. International Trade Commission has previously concluded that French state-owned enterprises have undersold U.S. producers of enriched uranium (*see* Chapter VII). Unlike SOEs in Russia, Kazakhstan, Uzbekistan, and China, French nuclear entities are partially owned by private companies and are somewhat subject to market pressures. Furthermore, the French nuclear market is not closed off to the U.S. or other uranium producers, and U.S. companies reported sales to France between 2014 and 2018. In contrast, U.S. uranium producers cannot sell into the Russian or Chinese markets, as these countries are served only by their state-owned enterprises.

[71] Russia has recently finished construction of Iran's only operating nuclear reactor at Bushehr, and Rosatom is the sole fuel supplier for the plant. Rosatom is also actively constructing the Akkuyu nuclear plant in Turkey, and is pursuing projects in Finland, Hungary, Bangladesh, Egypt and Belarus. *http://www.world-nuclear.org/information-library/current-and-future-generation/plans-for-new-reactors-worldwide.aspx.*

[72] ''Nuclear Cooperation with Other Countries: A Primer.'' Congressional Research Service. (January 15, 2019). *https://fas.org/sgp/crs/nuke/RS22937.pdf.*

[73] Ernest J. Moniz, ''The National Security Imperative for U.S. Civilian Nuclear Energy Policy'', *Energy Futures Initiative* (July 12, 2017), *https://energyfuturesinitiative.org/news/2017/7/12/moniz-the-national-security-imperative-for-us-civilian-nuclear-energy-policy.*

[74] [TEXT REDACTED].

[75] Commerce Department Survey of U.S. Nuclear Power Generation Sector, 2019.

E. Market Uranium Producers: Canada and Australia

Market uranium producers in Canada and Australia have historically performed better than their U.S. counterparts. Between 2014 and 2016, Canada and Australia increased their production of uranium by 59 percent and 26 percent, respectively.[76] In 2014, Canada opened the Cigar Lake mine and Australia opened the Four Mile mine,[77] both increasing overall production numbers.

These mines also exhibit positive geologic factors. Cigar Lake has an average ore grade of 14.5 percent uranium, one of the highest in the world. Higher ore grades require less processing to recover uranium from the ore, reducing overall production costs. Australia's largest mine, Olympic Dam, is also a significant producer of copper, gold, and silver.[78] Production of these commodities can therefore support continued uranium extraction even in the face of lower global spot prices.

Despite these geologic advantages, Canadian and Australian producers are also subject to the same market pressures caused by SOEs' overproduction. For example, McArthur River, estimated to have the world's largest deposit of high-grade uranium,[79] was idled in November 2017 by Cameco Resources due to poor economic conditions.[80] Australian mines have also cut production in response to poor market conditions between 2016 and 2018, most notably Olympic Dam cut production by eight percent and the Ranger mine by 10 percent.[81] As a result, between 2014 and 2018, 24.2 percent of uranium concentrate provided by Australian and Canadian companies to U.S. nuclear power generators came from Kazakhstan and Uzbekistan.[82]

Like their U.S. counterparts, Canadian and Australian producers cannot produce without regard for spot market price. SOEs' continued price-insensitive production therefore threatens all market uranium producers, including the U.S., Canada, and Australia.

VII. Findings

A. Uranium Is Important to U.S. National Security

As discussed in Part II, ''national security'' under Section 232 includes both (1) national defense and (2) critical infrastructure needs.

1. Uranium Is Needed for National Defense Systems

An assured supply of U.S.-origin uranium is critical to national defense for the purpose of nuclear weapons and the naval fleet. Nuclear reactors provide propulsion and electricity for key elements of the nation's naval fleet: 11 aircraft carriers and 70 submarines. Uranium is also vital for producing tritium, a radioactive gas used in U.S. nuclear weapons.

Many international nuclear cooperation agreements to which the United States is a party, including Section 123 agreements on civil nuclear cooperation, restrict the use of nuclear material imported under those agreements to peaceful uses. The United States requires U.S.-origin uranium and nuclear technologies for use in the production of uranium-based products for U.S. defense systems, with no foreign obligations that restrict the uses of such nuclear material.[83] At this time, there is only one functional enrichment facility in the United States. Located in Eunice, New Mexico and operated by the British-German-Dutch consortium URENCO, this enrichment facility may only enrich uranium for civil purposes; the material it produces may not be used for U.S. nuclear weapons or naval reactors.[84]

However, the U.S. has three defense systems that require highly-enriched uranium (HEU) (*see* Figure 23). The Department of Energy currently meets requirements for HEU by drawing on its stockpile. DOE also satisfies its ongoing need for HEU by recycling components from retired nuclear weapons. DOE is estimated to have approximately 575 tons of HEU and 80.8 tons of plutonium. Russia, in contrast, has an estimated 679 tons of HEU and 128 tons of plutonium.[85]

Furthermore, U.S.-origin uranium with no foreign obligation is required for the manufacture of tritium for defense purposes (*see* Figure 24). Tritium, a hydrogen isotope, is used in nuclear warheads to boost explosive yield. Tritium must be continually replenished in warheads because it has a short half-life of 12.3 years, decaying at a rate of 5.5 percent per year. The Department of Energy has an Interagency Agreement with the Tennessee Valley Authority (TVA) for production of tritium using the TVA's Watts Bar 1 commercial power reactor. TVA's Watts Bar 2 commercial power reactor will soon be used for tritium production as well.[86]

FIGURE 23: DEFENSE REQUIREMENTS FOR U.S.-ORIGIN URANIUM-BASED PRODUCTS

Submarines (70)—HEU Fuel.	Nuclear-Powered Aircraft Carriers (11)—HEU Fuel	Tritium Nuclear Weapons 3,800 +/− *.

* Includes 1,700 warheads on missiles and strategic bombers; 2,100 warheads in reserve; 150 warheads in Europe. An additional 2,500 warheads are slated for dismantlement.

Sources: U.S. Navy, International Panel on Fissile Materials (*www.fissilematerials.org*).

See Appendix J for entire chart.

[76] Nuclear Energy Agency & International Atomic Energy Agency. *Uranium 2018—Resources, Production and Demand,* 55. 2018. *http://www.oecd-nea.org/ndd/pubs/2018/7413-uranium-2018.pdf.*

[77] Ibid.

[78] Ibid., 134.

[79] Ibid., 159.

[80] ''Cameco: uranium prices too low to restart McArthur River mine operation.'' *MRO Magazine,* August 3, 2019. *https://www.mromagazine.com/2018/08/03/cameco-uranium-prices-too-low-to-restart-mcarthur-river-mine-operation/.*

[81] ''Australia's Uranium Mines.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-a-f/appendices/australia-s-uranium-mines.aspx.*

[82] U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power Generator Survey, Question 9.

[83] U.S. Department of Energy. *Tritium And Enriched Uranium Management Plan Through 2060,* iv. Report to Congress. (Washington DC: 2015) *http://fissilematrials.org/library/doe15b.pdf.*

[84] Agreement Between the Three Governments of the United Kingdom of Great Britain and Northern Ireland, the Federal Republic of Germany and the Kingdom of the Netherlands and the Government of the United States of America Regarding the Establishment, Construction and Operation of an Uranium Enrichment Installation in the United States, Washington, 24 July 1992, Treaty Series No 133 (2000).

[85] U.S. Department of Energy. *Tritium And Enriched Uranium Management Plan Through 2060.* Report to Congress. (Washington DC: 2015) *http://fissilematrials.org/library/doe15b.pdf.*

[86] February 2019 discussion between U.S. Department of Energy, National Nuclear Security Administration, Office of Major Modernization Programs and the U.S. Department of Commerce, Bureau of Industry and Security.

FIGURE 24: URANIUM REQUIREMENTS FOR U.S. NATIONAL DEFENSE

Material	Defense application	Other application
Natural Uranium (NU)	Enrichment	Materials Research Reactors.
Low Enriched Uranium (LEU).	Tritium Production for Nuclear Weapons	Medical Isotope Production.
Highly Enriched Uranium	Reactor Fuel for Aircraft Carriers and Submarines	U.S. High Performance Research Reactors.
Depleted Uranium U–235	Munitions—Kinetic Energy Penetrators	Mixed-Oxide Reactor Fuel.
	Munitions—Armor	Triuranium Octoxide (U3O8).
	Radiation Shielding	Uranium Hexafluoride (UF6).
	Targets for Pu–239 Production	Aircraft Parts.

Source: U.S. Department of Commerce, Bureau of Industry and Security; U.S. Department of Energy, February 2019.

Low-enriched uranium (LEU)[87] is used to produce tritium and to supply fuel to U.S. research reactors. DOE meets some of its internal demands for LEU by downblending HEU into LEU.[88] DOE uses a bartering program of uranium derived from HEU as payment for services to defray cleanup costs at the Portsmouth Gaseous Diffusion Plant in Piketon, Ohio.[89] The downblending practice also provides high assay low-enriched uranium (HALEU),[90] which is used in research reactors and medical isotope production reactors.

Lastly, DOE's downblending program for production of LEU fuel used in TVA reactors requires a supply of natural uranium trioxide (UO3) to be used as a diluent in the downblending process. As of 2019, there is no U.S. production of UO3; consequently, TVA has to import it from Canada and swaps unobligated flags from DOE stocks of natural uranium in other physical forms. DOE does not maintain a stockpile of unprocessed uranium of any type. Furthermore, the stockpile of HEU allocated to production of HALEU is expected to be depleted by 2060[91] and DOE's supply of LEU will be exhausted around 2041. The Department anticipates that its HEU stockpile, at current projected rates of consumption for naval reactor operations, will be depleted between 2050 and 2059.[92]

The National Nuclear Security Administration maintains the American Assured Fuel Supply (AFS), which is a stock of low-enriched uranium for use by U.S. and foreign utilities during a serious fuel supply disruption.[93] The AFS contains 230 tons of LEU that was downblended from DOE's HEU stockpile.[94] This stock is not available for use by DOE/NNSA. Only civilian nuclear power plant operators may use the AFS.

U.S. national security relies on credible nuclear deterrence. A shortage of HEU to fuel aircraft carriers and submarines and LEU to support tritium production would undermine U.S. defense operations and readiness. Likewise, an inability to supply HALEU to research reactors and medical isotope manufacturers would be detrimental to several critical infrastructure sectors.[95] The supply of U.S.-mined uranium will be critical as a feedstock for producing LEU and HEU in an enrichment facility that is planned to serve national defense needs. Without economically viable uranium mining operations in the United States, the enrichment of nuclear materials for DOE defense missions will not be possible under present law and policies. Defense needs for uranium are not enough to financially sustain the U.S. front-end uranium industry.

Future Defense Needs: Microreactors

DoD is pursuing the deployment of small modular reactors and microreactors that will require HALEU fuel as early as 2027. DoD microreactors may require fuel that is free from peaceful use restrictions, including the peaceful use restrictions that are generally applied by foreign suppliers of nuclear material to the United States. The 2019 National Defense Authorization Act requires the Secretary of Defense to issue requirements for a pilot program to design, test, and operate micro-reactors by December 31, 2027.[96]

DoD's need for microreactors stems from its facilities' reliance on commercial electric power. At present, DoD installations consume 21 percent of total federal energy consumption in the United States, at a cost of approximately $3.7 billion per year. Fifty-three percent of all energy consumed by DoD is delivered as electricity, 99 percent of which is provided via the commercial grid.[97]

In the event of a power outage, many DoD installations have only diesel generators and a limited supply of on-site diesel fuel. An extended grid failure could severely limit DoD's ability to carry out domestic and foreign operations.[98] Microreactors would be expected to operate 24 hours per day without disruption and do not require frequent refueling. DoD installations could therefore continue normal operations in the event of an extended commercial grid disruption.

[87] Low-enriched uranium (LEU) is uranium enriched to less than 20% U–235. (Uranium used in power reactors is usually 3.5–5.0% U–235). High-enriched uranium (HEU) is uranium enriched to 20% U–235 or more. (Uranium used in weapons is about 90% enriched U–235.)

[88] For the purposes of this 232 investigation, downblending is the reduction of uranium enrichment levels to less than 20 percent, a low enriched uranium (LEU), which cannot be used in weapons, but is suitable for use as fuel in nuclear power plants and naval nuclear reactors.

[89] U.S. Government Accountability Office. *Nuclear Weapons: NNSA Should Clarify Long-Term Uranium Enrichment Mission needs and Improve Technology Cost Estimates, Report to Congressional Committees.* 14. [GAO–18–126], February 2018. *https://www.gao.gov/products/GAO-18-126.*

[90] High assay low-enriched uranium (HALEU)—Low-enriched U–235 uranium product that has enrichment levels higher than the 3.5–5%. HALEU U–235 uranium product can have enrichment levels approaching 20%, depending on the application.

[91] U.S. Department of Energy, National Nuclear Security Administration, Office of Major Modernization Programs, February 2019 discussion with the U.S. Department of Commerce, Bureau of Industry and Security.

[92] ''Estimate of Global HEU Inventories as of January 2017.'' International Panel on Fissile Materials. *http://fissilematerials.org.*

[93] In 2005, the U.S. Department of Energy set up the American Assured Fuel Supply (formerly Reliable Fuel Supply) with $49.5 million in funding from Congress. This entity supports the International Atomic Energy Agency's International Fuel Bank initiative—a back-up source of uranium for global supply disruptions.

[94] U.S. Department of Energy. *Notice of Availability: American Assured Fuel Supply,* **Federal Register** 76 no. 160, August 18, 2011, 51358.

[95] U.S. Department of Energy. National Nuclear Security Administration. *Report to Congress: Fiscal Year 2019 Stockpile Stewardship and Management Plan—Biennial Plan Summary.* (Washington, DC: 2018). *https://www.energy.gov/sites/prod/files/2018/10/f57/FY2019%20SSMP.pdf.*

[96] For this report, micro-reactors are defined as reactors generating no more than 50 megawatts (MWe) Section 327, John S. McCain National Defense Authorization Act 2019 (Pub. L. 115–233), *https://www.congress.gov/bill/115th-congress/house-bill/5515/text?format=txt.*

[97] Defense Science Board. Department of Defense. ''*Report of the Defense Science Board Task Force on DoD Energy Strategy, More Fight—Less Fuel,*'' *2.* (Washington, DC: 2008). *https://www.acq.osd.mil/dsb/reports/2000s/ADA477619.pdf.*

[98] Ibid.

DoD aims to deploy microreactors in 2027, or shortly thereafter. This timeline assumes that there are no major technical hurdles to overcome. In addition, there are environmental and reactor siting reviews to address. Should microreactors become viable on a commercial scale, large-scale adoption of microreactors will require significant amounts of HALEU. DoD currently can only supply its HALEU needs through DOE's downblending of highly-enriched uranium, the supply of which is limited.[99] Future deployment of micro-reactors for defense purposes will increase national defense requirements for uranium and emphasizes the need for a viable U.S. commercial uranium industry.

A healthy U.S. commercial uranium industry is essential for defense needs. As DoD does not anticipate requiring newly-mined uranium for some years, it is impractical to suggest that a privately-owned mine could afford to operate on standby awaiting future DoD purchases. DoD analysts have noted that it ''can be difficult to reconstitute a material capability if all expertise and market share is lost,'' as most recently seen with U.S. rare earth mineral producers. U.S. uranium producers must be able to attract sufficient commercial (*i.e.* nuclear power generator) business in the present market to ensure their availability for defense requirements in the future.

Future Defense Needs: Proposed Nuclear Submarine Production

The Department of the Navy recently submitted its Fiscal Year 2020 President's Budget, recommending the construction of 55 new battle force ships over the next five years.[100] Fourteen of these are nuclear-powered: Eleven *Virginia*-class submarines, two *Columbia*-class submarines, and one *Gerald R. Ford*-class aircraft carrier.

The *Virginia*-class and *Columbia*-class submarines both house reactors which contain enough fuel to last the life of the ship, roughly 33 and 40 years respectively, unlike previous models which required refueling and overhaul.[101] The *Ford*-class aircraft carrier requires refueling, but at a significantly lower rate than the *Nimitz*-class aircraft carriers it will replace. DOE's current projection of HEU stockpile consumption for naval reactors does not take into account the addition of these 14 new nuclear-powered vessels. If these vessels are built, the total naval demand for HEU fuel will increase beyond what NNSA has anticipated, thus accelerating the date by which the HEU stockpile will be depleted.

The Role of National Security in Nuclear Regulation

Since Congress passed the Atomic Energy Act in 1946, all legislation governing the nation's uranium and nuclear power generation industries has been written with an emphasis on national security functions. As envisioned by Congress, regulation of the U.S. uranium and nuclear power generation industries is to be conducted in support of national security objectives. Consequently, Congress has empowered federal agencies to intervene in support of continued domestic U.S. uranium production capacity on several occasions. A brief history of this legislation can be found in Appendix H.

2. Uranium Is Required for Critical Infrastructure

Uranium is also required to satisfy requirements associated with the 16 critical infrastructure sectors identified by the U.S. Government in the 2013 Presidential Policy Directive 21 (PPD–21)[102] (*see* Figure 25). Critical infrastructure, as defined by PPD–21, provides the ''essential services that underpin American society'' and ''are vital to public confidence and the Nation's safety, prosperity, and well-being.''[103]

FIGURE 25: CRITICAL INFRASTRUCTURE SECTORS

Chemical	Commercial facilities	Communications
Critical Manufacturing	Dams	Defense Industrial Base.
Emergency Services	Energy (Including Electric Power Grid)	Financial Services.
Food and Agriculture	Government Facilities	Healthcare and Public Health.
Information Technology	Nuclear Reactors, Materials, and Waste	Transportation Systems.
Water and Wastewater Systems		

Source: PPD–21; Department of Homeland Security.

U.S. nuclear power generators are specifically included in the Nuclear Reactors, Materials, and Waste sector. Additionally, as U.S. nuclear power generators are integral to the nation's commercial electric grid, they are also part of the Energy sector. PPD–21 specifically notes that the Energy sector supports all other sectors because of its ''enabling function.''[104] Consequently, as all critical infrastructure sectors are dependent on reliable supplies of electricity, 19 percent of which is provided by the nation's 98 nuclear reactors. Thus, uranium is needed to support all U.S. critical infrastructure sectors.

Changing Electricity Generation Markets Affect U.S. Nuclear Generators

One of the primary challenges to the viability of the U.S. uranium industry is the closure of U.S. nuclear power plants. The front-end U.S. uranium industry relies on nuclear power plant operators for approximately 98 percent of its business. Consequently, the uranium industry cannot survive without a healthy U.S. nuclear power generation sector. Between January 2013 and September 2018, U.S. utilities retired seven reactors at six nuclear power facilities—a loss of more than 5,000 megawatts (MW) of generation capacity. Another 12 reactors with a combined generation capacity of 11.7

[99] *Roadmap for the Deployment of Micro-Reactors for U.S. Department of Defense Domestic Installations.*'' Nuclear Energy Institute. October 4, 2018. *https://www.nei.org/CorporateSite/media/filefolder/resources/reports-and-briefs/Road-map-micro-reactors-department-defense-201810.pdf.*

[100] ''*Report to Congress on the Annual Long-Range Plan for Construction of Naval Vessels for Fiscal Year 2020.*'' Office of the Chief of Naval Operations. March 2019. *https://www.secnav.navy.mil/fmc/fmb/Documents/20pres/PB20%2030-year%20Shipbuilding%20Plan%20Final.pdf.*

[101] *S9G Nuclear Reactors: http://www.world-nuclear.org/information-library/non-power-nuclear-applications/transport/nuclear-powered-ships.aspx.*

[102] U.S. White House. Office of the Press Secretary. *Critical Infrastructure Security and Resilience.* Presidential Policy Directive 21. (Washington, DC: 2013) *https://obamawhitehouse.archives.gov/the-press-office/2013/02/12/presidential-policy-directive-critical-infrastructure-security-and-resil.*

[103] Ibid.

[104] Ibid.

gigawatts (GW) are scheduled to close within the next seven years.[105]

A majority of the current nuclear fleet was constructed in the 1970s and 1980s when large-scale bulk power generators, including nuclear plants, were considered the most cost-effective means of providing reliable electricity. Although these plants required significant capital expenditures for construction, low fuel and operating costs made them practical to operate on a near-constant basis.[106] Energy planners particularly recognized that large scale plants were well equipped to provide baseload generation capacity.[107]

However, lower-than-projected electrical consumption growth rates, combined with aggressive energy conservation efforts, prevented many utilities from operating the baseload nuclear power plants at optimal levels. Distorted electricity markets caused by current FERC-approved market rules and increased adoption of renewable energy resources, such as solar and wind, which are subsidized through Federal and state tax incentives, are resulting in increased cost sensitivity within the nuclear power industry and premature retirements of nuclear power generation units.[108]

[TEXT REDACTED] In this decreased demand environment, wind generators were able to compete through the Production Tax Credit (PTC) that allows them to produce at negative cost. Nuclear generators, in contrast, generally do not receive similar subsidies.

[TEXT REDACTED]		
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In addition to renewables, the introduction of highly efficient turbine gas generators and the wide availability of low cost natural gas, has changed the competitive landscape. Ten survey respondents indicated that their nuclear facilities faced significant challenges to their viability from natural gas-fired generators. Under current wholesale electricity pricing mechanisms, natural gas-fired generators are able to sell their electricity to the grid at lower costs than nuclear operators. This is partially due to the intermittent nature of natural-gas fired generation; natural gas-fired generators can be activated and deactivated as needed, whereas nuclear power generators have less operational flexibility. Similarly, subsidized renewable sources, such as solar and wind, are intermittent operators (*e.g.,* during daytime hours for solar, and favorable wind conditions for wind) and can be sold at a lower cost than constantly-running nuclear generators.

These factors create a situation that substantially disadvantages nuclear power generators. A 2017 IHS Markit study observed that, ''generating resources providing security of supply receive negative market-clearing prices because distorted market conditions drive rival subsidized suppliers to bid against each other to avoid the loss of output-based subsidy payments.'' [109] FERC, recognizing challenges faced by nuclear and other baseload generators, opened a proceeding in January 2018 to examine the relationship between grid reliability and wholesale market rules.[110] The proceeding will examine grid resilience pricing and consider how valuation deficiencies lead to premature retirements of fuel-secure generation, including nuclear. FERC, has not yet taken action to address the inequities of the markets that threaten the resilience of the Nation's electricity system.

Increased state energy efficiency standards and the predominance of the service sector in the economy, which does not consume as much energy as other sectors such as manufacturing, have slowed electricity demand growth. In 2017, the North American Electric Reliability Corporation (NERC) reported that the annual growth rate of peak demand reached record lows of 0.61 percent in summer and 0.59 percent in winter.[111] Slower growth in electricity demand places increased economic pressures on large-scale generators, including nuclear power plants.[112]

The increased presence of natural gas-fired and renewable power plants in the nation's electric generation grid does not obviate the need for nuclear power baseload generators. In fact, there is a continued role for nuclear power plants because they can provide a constant

[105] ''America's oldest operating nuclear power plant to retire on Monday.'' U.S. Energy Information Administration. September 14, 2018. *https://www.eia.gov/todayinenergy/detail.php?id=37055.*

[106] ''Advancing Past ''Baseload'' to a Flexible Grid- How Grid Planners and Power Markets Are Better Defining System Needs to Achieve a Cost-Effective and Reliable Supply Mix,'' 1. The Brattle Group. June 26, 2017. *http://files.brattle.com/system/publications/pdfs/000/005/456/original/advancing_past_baseload_to_a_flexible_grid.pdf?1498246224.*

[107] Roughly defined, baseload generation capacity refers to generation capacity that can provide ''relatively low-cost electricity production to meet around-the-clock electricity loads''. Ibid., 5.

[108] The Federal Energy Regulatory Commission (FERC or the Commission) has recognized that there are deficiencies in the way the regulated wholesale power markets price power (''price formation,'' *i.e.,* energy, capacity, and ancillary services) and has developed an extensive record on price formation in the Commission-approved ISOs and RTOs.

[109] ''*Ensuring Resilient and Efficient Electricity Generation: The Value of the current diverse US power supply portfolio.*'' IHS Markit. April 2018. [hereinafter IHS Ensuring Resilient and Effective Electricity Generation].

[110] FERC acknowledges that that there are deficiencies in the way the regulated wholesale power markets price power (''price formation,'' *i.e.,* energy, capacity, and ancillary services) and has developed an extensive record on price formation in the Commission-approved ISOs and RTOs. FERC ''Grid Resilience in Regional Transmission Organizations and Independent System Operators,'' Docket No. AD18–7–000 (January 2018)

[111] ''Long Term Reliability Assessment,'' 12. North American Reliability Electric Reliability Corporation. December 2018. *https://www.nerc.com/pa/RAPA/ra/Reliability%20Assessments%20DL/NERC_LTRA_2018_12202018.pdf.*

[112] In 1990, the compound annual growth rate in demand for both summer and winter exceeded 2%. Ibid.

flow of electricity to the grid and do not require constant deliveries of fuel from external sources. Nuclear power plants can produce at near-full capacity when solar and wind generation facilities cannot produce electricity.

Similarly, natural gas plants are reliant on ''just-in-time'' deliveries of natural gas, and natural gas storage capacity in the U.S. is severely limited in many regions.[113] A North American Electric Reliability Corporation (NERC) report noted that only 27 percent of U.S. natural gas-fired generation capacity installed since 1997 is capable of dual fuel usage, which uses alternative fuel such as diesel to maintain generation.[114] Natural gas pipelines are also vulnerable to cyberattack, which can disable pipeline operations and cut off gas supply.[115]

In contrast, nuclear generators are not subject to similar potential disruptions or energy storage limitations since they have long refueling cycles between 18 and 24 months, and do not require constant fuel deliveries. These refueling operations are planned well in advance, allowing both plant and transmission system operators to make arrangements for alternative generation capacity. All survey respondents indicated that they could maintain normal generation operations even with a missed delivery of uranium concentrate, uranium hexafluoride, or enriched uranium. Respondents indicated that they maintain sufficient inventory of the above products and have layered contracts with multiple suppliers. Any single missed delivery could therefore be addressed with existing inventory.

Respondents identified missed deliveries of fabricated fuel prior to a scheduled refueling as the greatest threat to continue operation. [TEXT REDACTED]

Based on the nature of the nuclear supply chain, nuclear power generators are comparatively more resilient than other power generation sources that require constant fuel deliveries. As presented in Chapter VII, U.S. nuclear power generators can use U.S.-sourced uranium to meet their power needs, potentially avoiding situations where U.S. utilities would be reliant on last-minute imports of natural gas or other materials to address shortfalls.[116] Leveraging the unique operational characteristics of nuclear power generators and the unused capacity of the U.S. uranium industry can ensure greater grid reliability.

B. Imports of Uranium in Such Quantities as Are Presently Found Adversely Impact the Economic Welfare of the U.S. Uranium Industry

1. U.S. Utilities' Reliance on Imports of Uranium in 1989

In September 1989, the Secretary completed a Section 232 investigation on the effect of uranium imports on the national security. The investigation, requested by the Secretary of Energy, determined that U.S. utilities imported a significant share of their uranium requirements. At the time, imports of uranium concentrate accounted for roughly 51 percent of domestic utility demand.[117] The 1989 investigation also found that U.S. uranium producers faced strong foreign competition, particularly from the Soviet Union. It further reported that employment in the industry was steadily decreasing.[118]

[TEXT REDACTED] [119]

Consequently, the Secretary concluded that uranium was not being imported into the United States under such quantities or circumstances that threatened to impair the national security. For more discussion of the 1989 Section 232 investigation, refer to Appendix G.

2. U.S. Utilities' Reliance on Imports of Uranium Continue To Rise

U.S. utilities' reliance on foreign suppliers to meet their uranium product and service requirements have continued to increase since the 1989 uranium 232 investigation. In 2018, U.S. nuclear utility operators relied on foreign suppliers for 93.3 percent of their uranium concentrate requirements, 85.5 percent of their uranium hexafluoride requirements, and 97.6 percent of their enriched uranium hexafluoride (UF6) requirements. As for uranium service requirements, U.S. nuclear utility operators relied on foreign suppliers for 42.3 percent of their conversion service requirements and 61.5 percent of their enrichment service requirements from 2014 to 2018 (*see* Figure 27).

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[113] ''Special Reliability Assessment: Potential Bulk Power System Impacts Due to Severe Disruptions on the Natural Gas System,'' 10. North American Electric Reliability Corporation. November 2017. *https://www.nerc.com/pa/RAPA/ra/Reliability%20Assessments%20DL/NERC_SPOD_11142017_Final.pdf.*

[114] Ibid.

[115] Blake Sobczak, Hannah Northey, and Peter Behr, ''Cyber raises threat against America's energy backbone'', *E&E News* (May 23, 2017), *https://www.eenews.net/stories/1060054924/.*

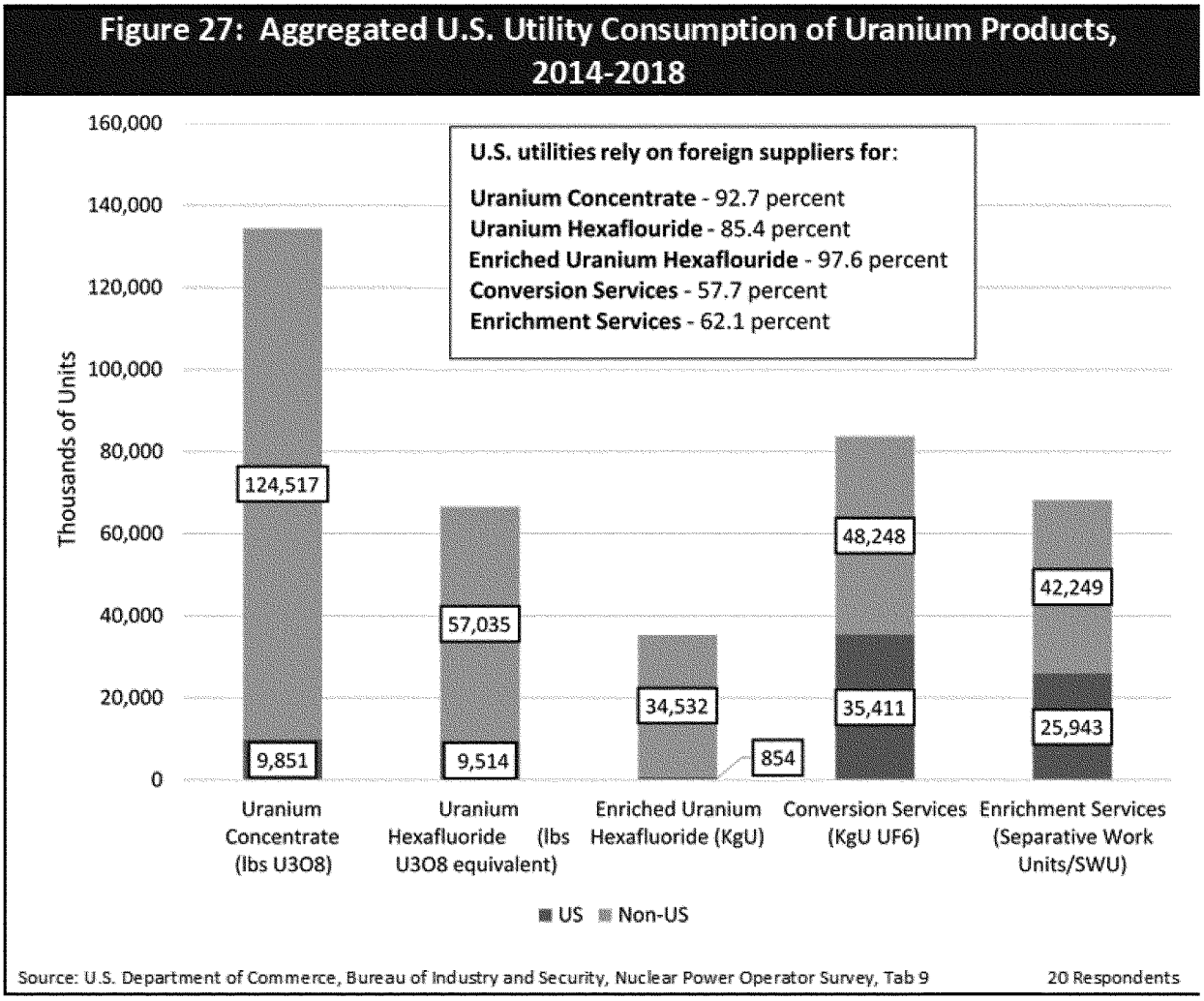
[116] During extreme cold temperatures in January 2018, Distrigas of Massachusetts had to import liquefied natural gas from Russia to address a gas shortage in the region.

Chesto, Jon. ''Russian LNG Is Unloaded in Everett; the Supplier (but Not Gas) Faces US Sanctions.'' *Boston Globe,* January 30, 2018. *https://www.bostonglobe.com/business/2018/01/29/tanker-unloads-lng-everett-terminal-that-contains-russian-gas/rewj1wKjajaKtLp79irzTI/story.html.*

[117] 1989 Report, I–2.

[118] *Id.* III–10 and III–27.

[119] Ibid., V–4 to V–5.



In 2018, U.S. imports of uranium products reached a 10-year low in terms of both total quantity and aggregate value. Imports peaked in both terms in 2011, when 40 million pounds of uranium products were imported, at a total value of $5.3 billion USD.[120] However, the Fukushima incident occurred in the same year, and both figures have since declined, reaching a total of just over 19 million pounds in 2018 (a 52 percent decrease), for a combined value of $2.2 billion USD (a 58 percent decrease)[121] (*see* Figures 28 and 29).

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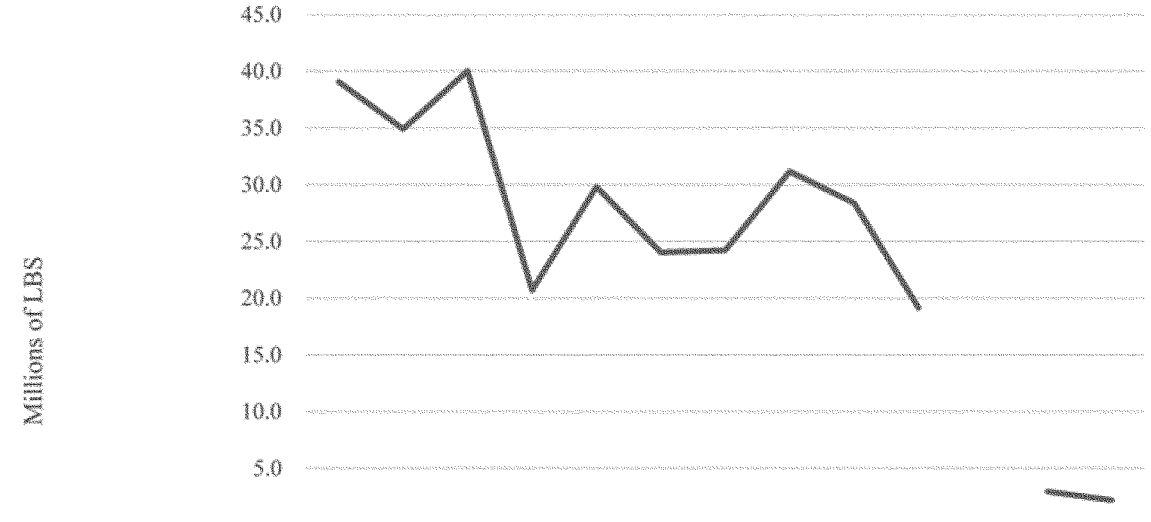
[120] USITC Dataweb.

[121] USITC Dataweb.

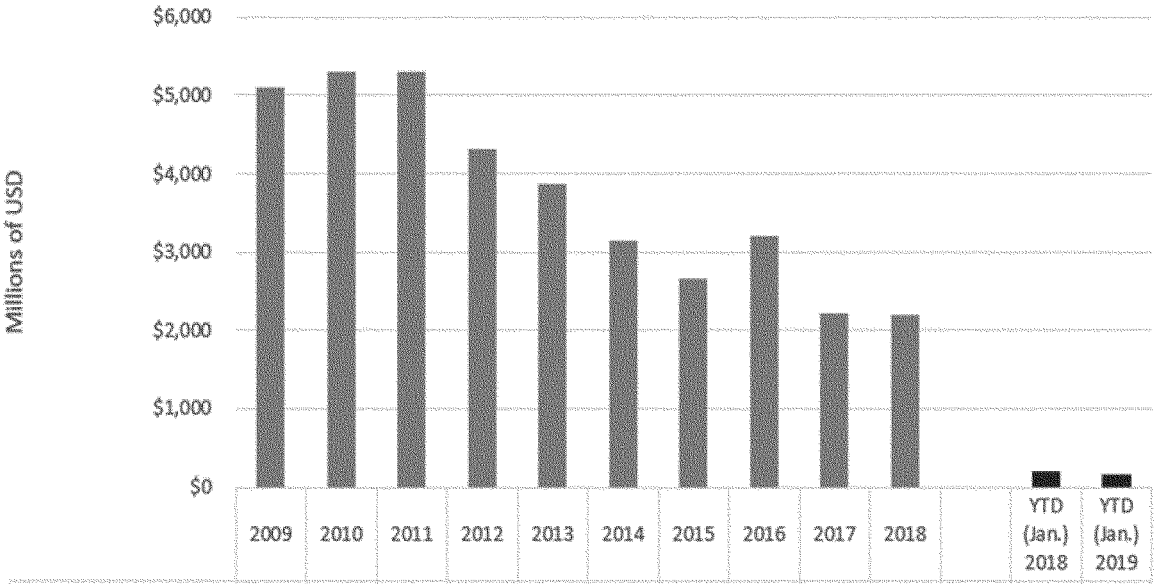
Figure 28: U.S. Imports of Uranium Products



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018		YTD (Jan.) 2018	YTD (Jan.) 2019
Quantity (Millions LBS)	39.1	34.9	40.0	20.7	29.8	24.0	24.2	31.2	28.4	19.1		3.0	2.2

Source: USITC Dataweb Updated 3.18.2019, HTS Codes: 2612.10.00, 2844.10.20, 2844.20.00, 2844.10.10, 2844.10.50, 2844.30.20, 2844.30.50

Figure 29: Value of U.S. Imports of Uranium Products



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018		YTD (Jan.) 2018	YTD (Jan.) 2019
Value (Millions of USD)	$5,096	$5,308	$5,303	$4,318	$3,879	$3,137	$2,667	$3,197	$2,222	$2,207		$201	$172

Source: USITC Dataweb Updated 3.18.2019, HTS Codes: 2612.10.00, 2844.10.20, 2844.20.00, 2844.10.10, 2844.10.50, 2844.30.20, 2844.30.50

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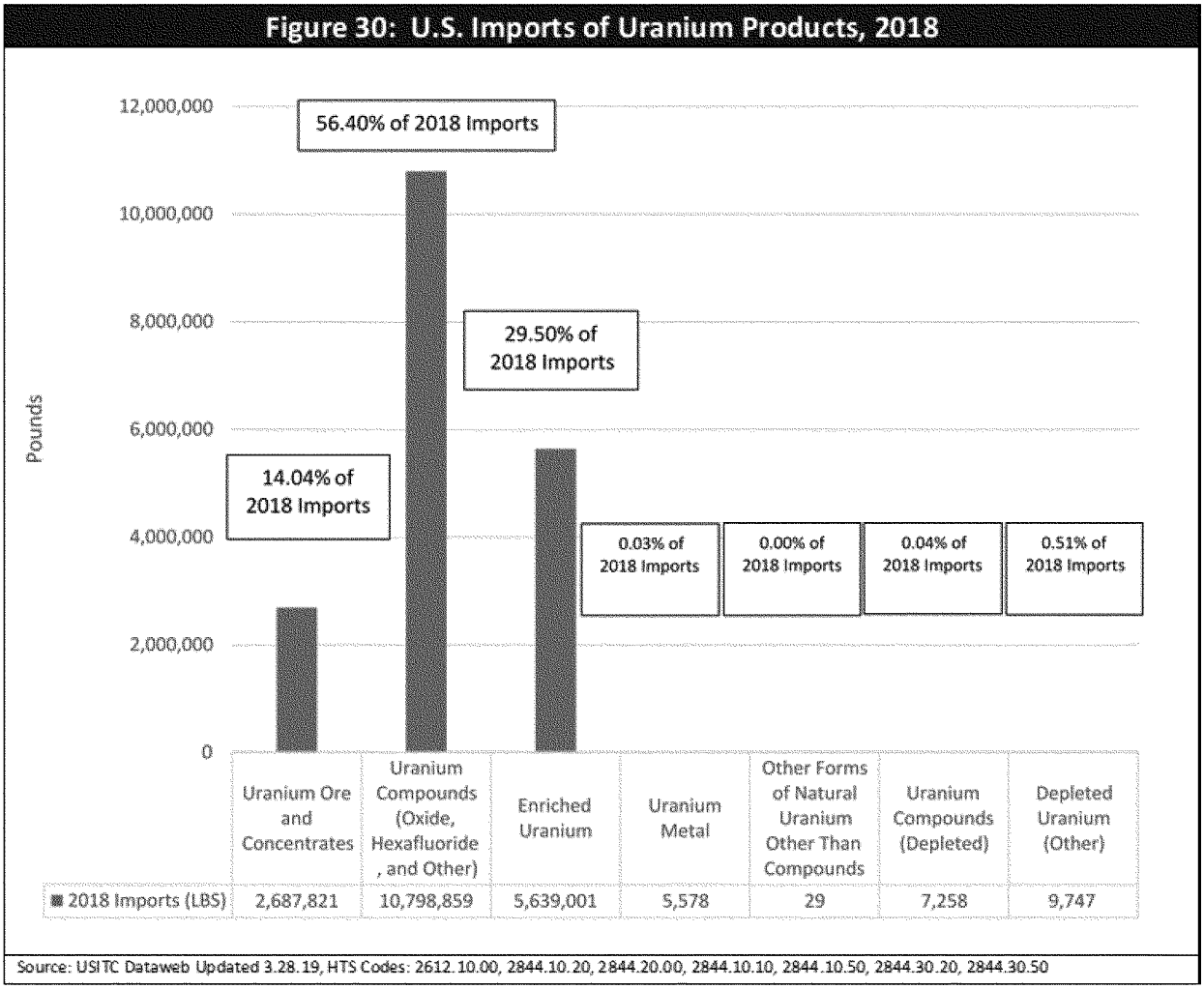
The HTS codes that represent uranium products are broken out by materials that represent the different stages of the fuel cycle that uranium ore goes through to become a nuclear fuel assembly. The total composition of 2018 imports of uranium products was comprised of a little over half (56.4

percent) of uranium compounds (oxide, hexafluoride, and other) and about one-third (29.5 percent) of enriched uranium (*see* Figure 30). Fuel assemblies are not listed in Figure 30 due to the fact that from 2014 to 2018, no fuel assemblies imported into the U.S. were for actual use by U.S. nuclear electric power operators. During this time period imported fuel assemblies where either test assemblies or products that were being returned to the original manufacture.[122]



3. High Import to Export Ratio

U.S. imports of uranium products, which displace demand for domestic uranium and lower production at U.S. mines, reached 2.7 times the level of exports of U.S. uranium products in 2013 (*see* Figure 31). In 2018, U.S. import levels were 2.2 times the level of exports of U.S. uranium products. Uranium production from state owned enterprises continues to depress world uranium spot prices, making it increasingly difficult for U.S. companies to export their uranium products. In 2018, 98 percent of U.S. uranium exports were made up of ''uranium compounds, uranium metal, and other forms of natural uranium,'' 1.8 percent was ''enriched uranium'', and 0.2 percent was ''depleted uranium'' (*see* Figure 32).

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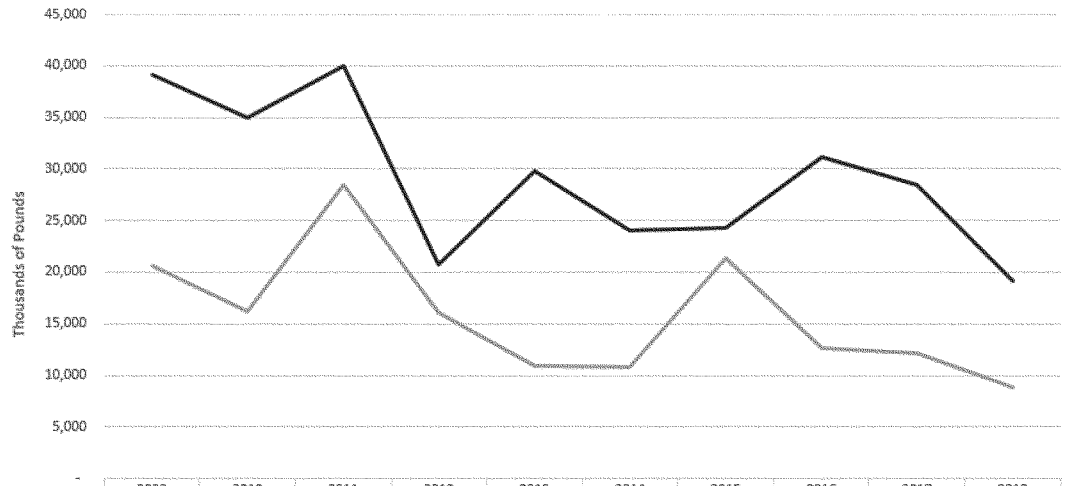
[122] Department of Energy, Nuclear Security Administration, Nuclear Materials Management and Safeguard System.

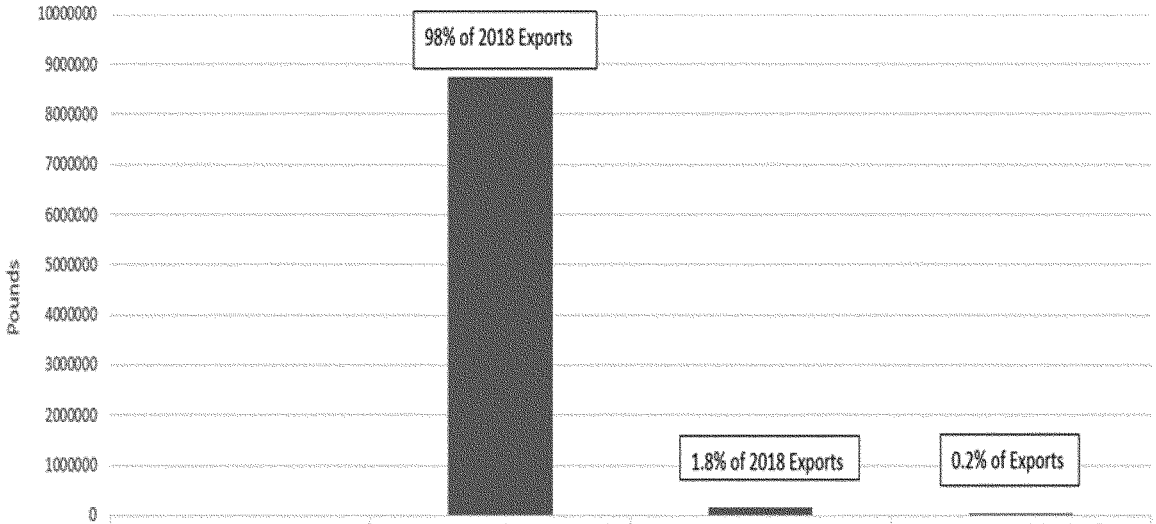
Figure 31: U.S. Imports and Exports of Uranium Products



	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Imports (Thousands of LBS)	39,074	34,910	40,030	20,710	29,818	24,044	24,231	31,171	28,390	19,148
Exports (Thousands of LBS)	20,659	16,134	28,423	16,025	10,956	10,858	21,348	12,580	12,098	8,892

Source: Global Trade Atlas Updated 4.12.2019, HTS Codes: 2612.10, 2844.10, 2844.20, 2844.30.20, and 2844.30.50

Figure 32: U.S. Exports of Uranium Products, 2018



	Uranium Ore and Concentrates	Uranium Compounds, Uranium Metal, and Other Forms of Natural Uranium	Enriched Uranium	Uranium Compounds (Depleted) and Depleted Uranium (Other)
2018 Exports (LBS)	0	8,735,225	155,541	1,122

Source: USITC Dataweb Updated 3.28.19, HTS Codes: 2612.10.00, 2844.10.20, 2844.20.00, 2844.10.10, 2844.10.50, 2844.30.20

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4. Uranium Prices

The Department's 1989 uranium 232 investigation identified several trends responsible for the decline in global uranium prices, including increased production from lower-cost ore bodies in Canada, Australia, and South Africa; dumping of Russian, Kazakh, and Uzbek material on the global enriched uranium market; and cancellations of proposed reactors in the U.S. and other Western nations.[123]

Many of these trends persisted well after 1989, and following the dissolution of the Soviet Union, uranium sales from Russia, Kazakhstan, and Uzbekistan continued to influence both the U.S. and global uranium markets. As detailed in the end of this section, the U.S. Government addressed the impact of these sales of subsidized uranium through anti-dumping investigations and the imposition of suspension agreements.

[123] 1989 Report. III–12 to III–14 and III–26 to III–27.

At the same time, other imports from the former Soviet Union continued to depress uranium prices. Under the 1993 Megatons to Megawatts program [124] (officially the ''Agreement Between the Government of the United States of America and the Government of the Russian Federation Concerning the Disposition of Highly Enriched Uranium Purchase Agreement''), the U.S. and Russian governments agreed to the conversion of 500 metric tons of HEU from dismantled ex-Soviet nuclear weapons into LEU, which was ultimately sold to U.S. utilities. Between 1993 and 2013, this program resulted in the introduction of 14,000 metric tons of LEU into the U.S. nuclear fuel market, directly competing with U.S. uranium production.

Demand in the United States for nuclear power also stagnated after 1989. The Tennessee Valley Authority's Watts Bar 1, which came online in 1996, was the only nuclear reactor completed in the United States between 1989 and 2016. Between 1989 and 2000, nine reactors were decommissioned and no new reactors were authorized. Lack of domestic demand, spurred in part by competition from other generation sources and public opposition to new nuclear power projects after the Three Mile Island and Chernobyl incidents, were factors that contributed to low uranium prices during this period. By November 2000, uranium spot market prices had fallen to $7.13 per pound; a 56 percent decrease from the July 1996 high of $16.50 and a 39 percent decrease from the January 1989 price of $11.60.

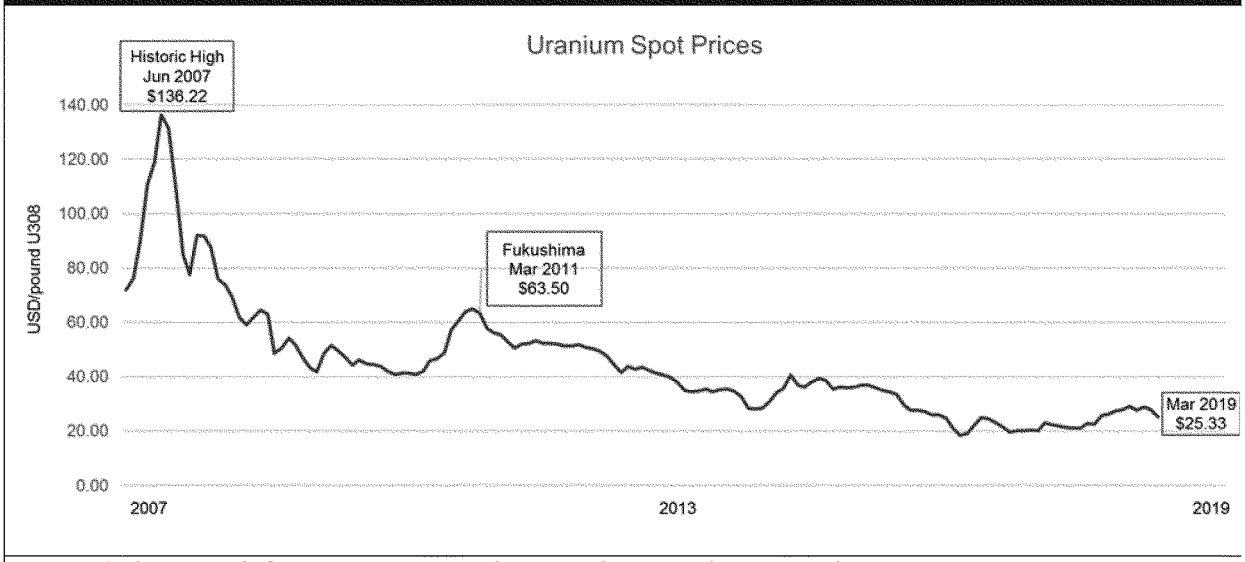
Uranium prices then began to climb beginning in fall 2001, and by November 2001, the spot price reached $9.43. The price then climbed exponentially thereafter, reaching $13.18 in November 2003, $33.55 in November 2005, and a record $136.22 in June 2007—a 1,810 percent increase on the November 2000 price. The principal driver of this price increase was a trend widely referred to as the ''nuclear renaissance,'' which anticipated the construction of dozens of reactors worldwide.

Influenced, in part, by increasing oil and natural gas prices, as well as, public concern about carbon emissions, many Western governments adopted policies intended to promote the construction of new nuclear power generators. In the United States, the Energy Policy Act of 2005 provided financial incentives for the construction of new nuclear plants, including a production tax credit and guarantees for construction loans.[125] U.S. utilities took advantage of these policy changes and applied for construction and operating licenses for 25 new reactors between 2007 and 2009.[126]

Most of these reactors, however, were not built. As discussed earlier, the March 2011 Fukushima incident prompted a groundswell of public opposition to new nuclear power generation. Additionally, competition from low-cost gas fired turbine generators made plans for many nuclear plants economically unfeasible. Of the 25 reactor applications submitted between 2007 and 2009, only three will be completed by 2022. The remaining reactor plans were cancelled due to a variety of factors, including public reaction to the Fukushima incident and falling electricity prices.

The Fukushima incident and subsequent cancellation of proposed new reactors created a global uranium oversupply. The uranium spot market price fell from $63.50 in March 2011 to $42.28 by March 2013. By March 2017, the price had fallen to $24.55—a 61 percent decline from the March 2011 price (*see* Figure 33).

Figure 33: Spot Market Price of Uranium, 2007 – Present



Source: Federal Reserve Bank of St. Louis, Economic Research Division and International Monetary Fund

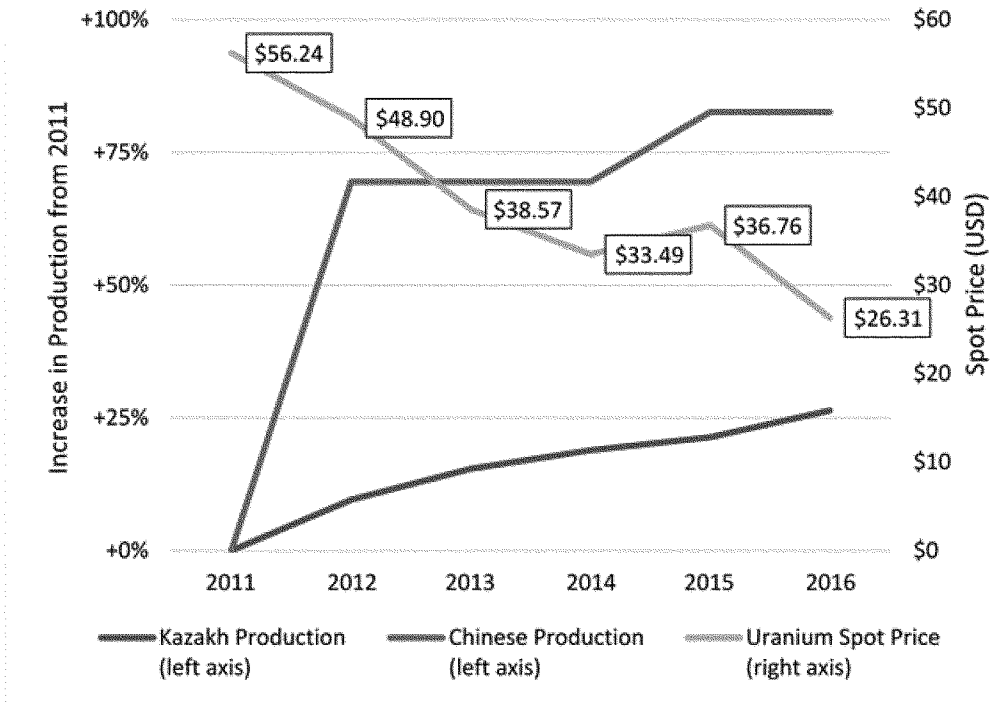
[124] ''Megatons to Megawatts program will conclude at the end of 2013.'' U.S. Energy Information Administration. (Washington, DC: 2013). *https://www.eia.gov/todayinenergy/detail.php?id=13091.*

[125] ''Nuclear Power in the USA.'' World Nuclear Association. *http://world-nuclear.org/information-library/country-profiles/countries-t-z/usa-nuclear-power.aspx.*

[126] Rascoe, Ayesha. ''U.S. Approves First New Nuclear Plant in a Generation.'' *Reuters,* February 9, 2012. *https://www.reuters.com/article/us-usa-nuclear-nrc/u-s-approves-first-new-nuclear-plant-in-a-generation-idUSTRE8182J720120209.*

In the years following the Fukushima incident, U.S. uranium producers closed or idled 22 facilities, including mining, milling, conversion, enrichment, fuel fabrication, and R&D operations. As U.S. uranium producers ceased production due to poor market conditions, state-owned uranium enterprises increased output. According to available data, Kazakh and Chinese output had strong increases during the 2011 to 2016 period, even when global spot market prices were decreasing post-Fukushima incident (*see* Figure 34).

Figure 34: Foreign Production and Uranium Spot Market Price, 2011 - 2016



Source: World Nuclear Association; Federal Reserve Bank of St. Louis

Between 2011 and 2016, Kazakhstan's uranium production increased by 26 percent.[127] Similarly, China increased domestic uranium production by 83 percent during the same period.[128] These increases in production during a 61 percent decline in global uranium spot market prices further increased imports into the U.S., and highlights the ability of state-owned uranium enterprises to distort markets and disadvantage U.S. producers.

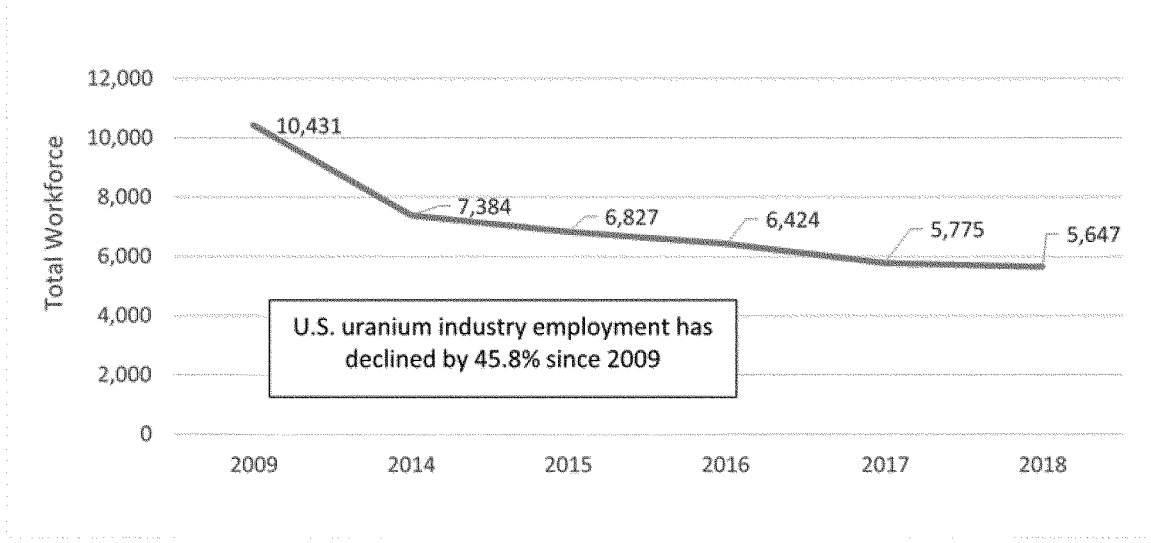
5. Declining Employment Trends

Employment in the U.S. front-end uranium industry has experienced steady declines over the surveyed years of 2014 to 2018. Data regarding employment in 2009 was collected in order to observe the levels of employment pre-Fukushima and post-Fukushima. As anticipated, between 2009 and 2018, miners, millers, converters, and enrichers experienced drastic decreases in workforce numbers. Overall employment in the front-end uranium industry declined by 45.8 percent over this period (*see* Figure 35).

[127] ''Uranium and Nuclear Power in Kazakhstan.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-g-n/kazakhstan.aspx.*

[128] ''Uranium Production Figures, 2008–2017.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/facts-and-figures/uranium-production-figures.aspx.*

Figure 35: U.S. Uranium Industry Employment, Front-End, 2009 and 2014-2018



NOTE: 2009 included to show realistic levels of employment pre-Fukushima; Includes miners, millers, converters, enrichers, and fuel fabricators.

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 10 — 32 respondents

U.S. Front-End Uranium Industry Employment

For uranium miners, the decline in employment has been evident since the 1989 uranium 232 investigation. Indeed, the peak of uranium mining employment was 21,951 workers in 1979, but by 1989, employment had fallen 91 percent to just 2,002 workers.[129] Survey data shows that employment has further decreased since the 1989 uranium 232 investigation and steadily declined by 54.6 percent between 2009 and 2018, with further declines projected for 2019 (*see* Figure 36).

[129] 1989 Report. III–10.

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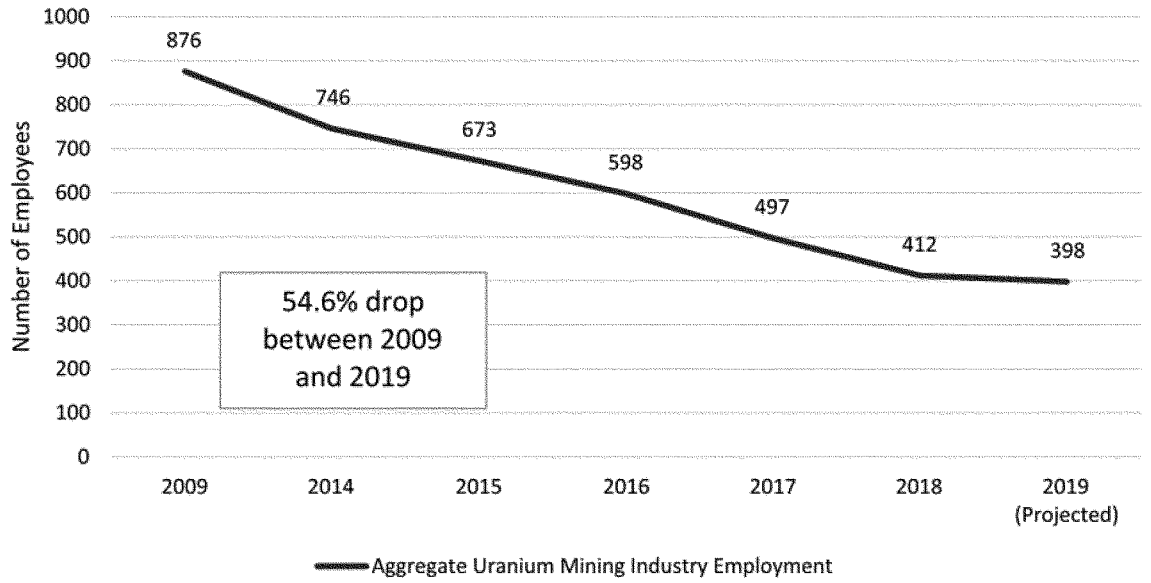
Figure 36: U.S. Uranium Miners and Millers, Industry Employment



NOTE: 2009 included to show realistic levels of employment pre-Fukushima

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 10 — 20 Respondents

Events in the nuclear electric utility sector over the past 40 years have adversely affected uranium mining industry employment levels. Notably, the 1979 Three Mile Island accident and the 2011 Fukushima incident prompted significant downturns in the industry and caused steep declines in mining employment.

Mining employment is also affected by spot market prices. High spot market prices correspond with higher employment, while lower prices cause mines to idle and increased unemployment. The combined repercussions of the Fukushima incident and low spot market prices can be seen in the U.S. front-end uranium industry, as companies continue to cut workforce numbers and idle production.

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [130]

[TEXT REDACTED]
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[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED]

[130] [TEXT REDACTED].

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED]
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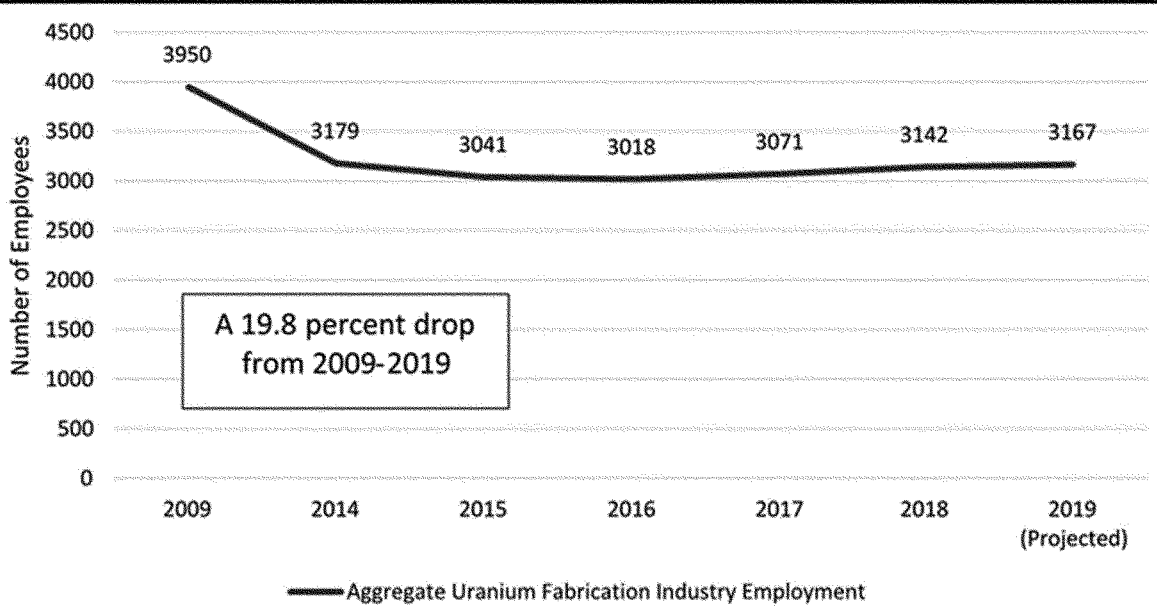
Fuel fabricators have seen a 19.8 percent decrease in workforce numbers since 2009. This moderate decrease is expected, as the vast majority of fabrication of fuel assemblies is still produced domestically due to the highly engineered nature of the final products. Decreases in domestic demand and poor market conditions have affected domestic fuel fabricators, and workforce cuts were made in response to financial difficulties and reported bankruptcies (*see* Figure 39).

Figure 39: U.S. Uranium Fabricators, Industry Employment



NOTE: 2009 included to show realistic levels of employment pre-Fukushima

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 10 — 4 Respondents

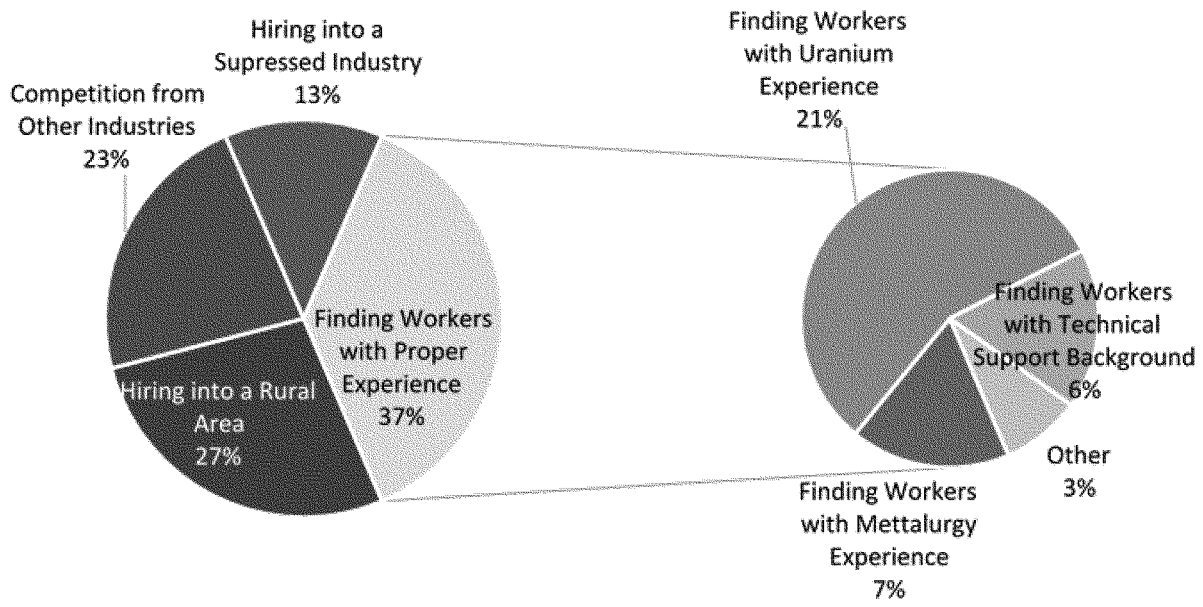
The substantial decreases observed in the front-end domestic uranium industry can have adverse effects on competitiveness and long-term production in the industry. The entirety of the front-end uranium industry

requires a specialized workforce which consists of a wide range of expertise and education levels. Some skillsets within the industry are transferable to other applications. However, an aging workforce can mean the loss of knowledge and skillsets specific to the uranium industry as workers continue to transfer industries and retire. According to the Department's 2019 survey data, the average age of specialized workers in the front-end industry is roughly 50 years old. Should workforce numbers continue to decrease, specialized workers will become increasingly difficult to hire or re-hire in the event of a market upswing due to both retirement and competition from other industries. Department survey data indicates various difficulties in hiring and retaining workers in the front-end uranium industry (*see* Figure 40).

Front-end uranium companies may be able to fill vacancies should production resume or increase, but difficulties in obtaining skilled employees will take time and investment. A lack of available skilled employees will require training new hires, thus adding additional costs. [TEXT REDACTED]

Efforts to recruit personnel are also complicated by the remote location of many uranium mines. Over half of the mining/milling respondents indicated that their facilities' rural location imposed a significant barrier to recruitment and retention. [TEXT REDACTED]

Figure 40: Difficulties Hiring and Retaining Workers in the Uranium Industry



Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 10 — 32 Respondents

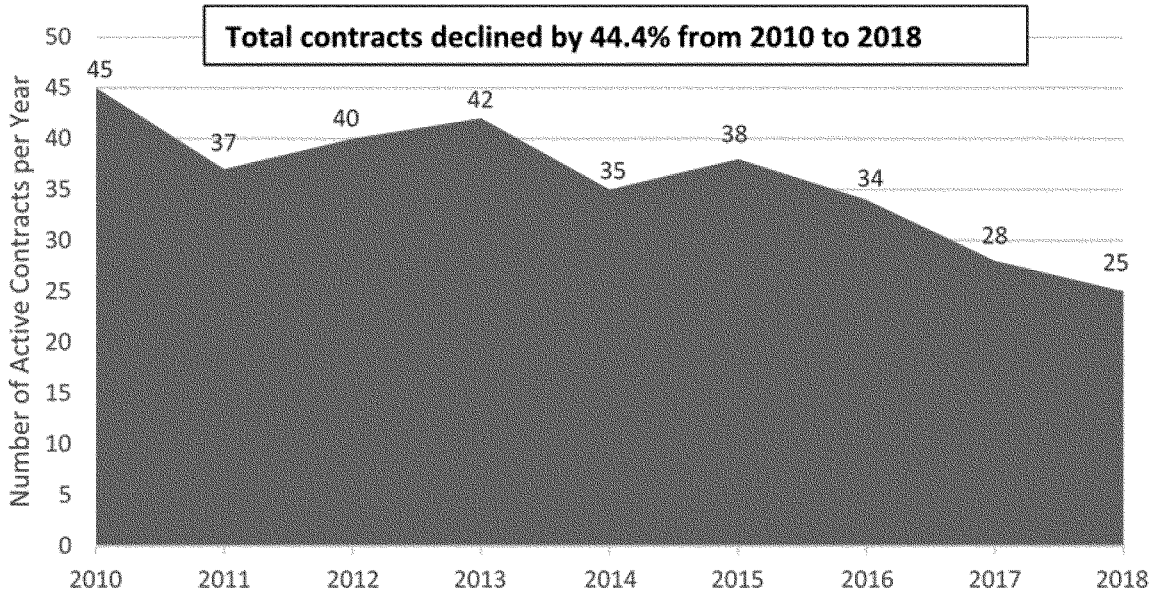
In the event of a major production increase, current employment levels and the trending decline in employment in all industries associated with the front-end uranium industry indicate that production needs would not be met by the current workforce, and significant additional hiring would be required (*see* Figure 41).

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

6. Loss of Domestic Long Term Contracts Due to Imported Uranium

Front-end uranium industry companies in the U.S. have experienced a decline in new or renewed contracts over the last decade. From 2010 to 2018, the number of active contracts for domestic front-end uranium industry companies, including miners, millers, converters, enrichers, and fuel fabricators, declined by 46.7 percent (*see* Figure 42).

Figure 42: Number of Active Front-End Contracts 2008-2018



Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 9a

12 Respondents

These expiring contracts are not being offset by new contracts. From 2010 to 2018, the total number of new contracts extended to front-end companies fell by 76.2 percent. [TEXT REDACTED] This is evident by the decline in newly formed long-term contracts. Long-term contracts have fallen by 92.3 percent since 2010 and only one contract was signed in 2018.

In particular, long-term contracts for U.S. miners and millers fell by 71.4 percent, with just two active long-term contracts in 2018 (*see* Figure 43). The number of contracts that front-end companies retain is likely to fall further, as long-term contracts from previous years are set to expire. [TEXT REDACTED]

Figure 43: Types of Contracts – Millers and Miners, 2008-2018

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 9a

12 Respondents

7. Financial Distress

The 1989 uranium 232 investigation found that the front-end uranium industry was not financially viable during the period of the investigation.[131] Since these findings, increasing volumes of imported uranium have further crippled the financial health of the domestic front-end uranium industry. Uranium miners, converters, and enrichers have all felt the detrimental effects of decreasing market shares due to drastically increasing levels of imports. According to survey data, key points in the front-end uranium industry experienced increasing debt ratios and critically low profit margins during the 2014 to 2018 period. An assessment of financial risk for all surveyed uranium miners, converters, enrichers, and fuel fabricators is shown in Figures 44a and 44b.[132]

[131] 1989 Report. I–2.

[132] Financial risk is evaluated based on survey data including balance sheets and income statements. Many of the companies classified as Low/Neutral Risk provided no information or do not incur many costs due to being idled, shutdown or having undeveloped deposits. Low/Neutral Risk is not necessarily an indication that they are not financially struggling but indicates in the near term they are unlikely to go out of business.

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

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[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

[TEXT REDACTED] Uranium Miners

The financial health of uranium mining companies has deteriorated to even more unsustainable levels than at the time of the 1989 uranium 232 investigation.[133] As a result of the consolidation and homogenization of the industry in the past 30 years, financial struggles during market downturns have been magnified. U.S. uranium mining companies continue to struggle to compete in a market with low spot market prices that do not cover production costs, increasing imports from SOEs, and static/declining domestic demand. Should current market conditions continue, U.S. uranium miners will not be able to sustain operations for much longer.

The 1989 Uranium 232 Investigation found that a, ''characteristic of the uranium mining industry is that few companies are exclusively dependent on the production and sale of the ore. Uranium production is usually a relatively small part or byproduct of other major activities of the firm.'' [134] This is a material difference between the state of uranium mining during the 1989 uranium 232 investigation and the uranium mining industry today. According to Department survey data, a majority of the 20 companies in today's domestic uranium mining industry depend exclusively on uranium mining for financial viability, and do not have the support of diverse business lines that would offset losses in their uranium mining activities.

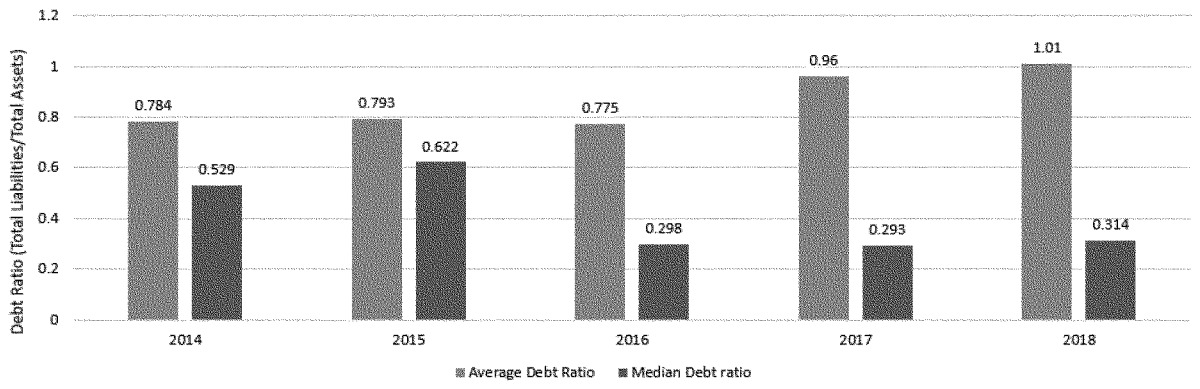
The trend in industry debt ratios for the 2014 to 2018 period is worsening (*see* Figure 45). The increasing average and stable median for approximately half of the companies surveyed implies poor performance in managing debt. [TEXT REDACTED] The increase in debt

[133] 1989 Report III–1 to III–2.

[134] 1989 Report. III–2.

ratios one observes can reasonably be attributed to companies actively engaged in unprofitable uranium mining operations.

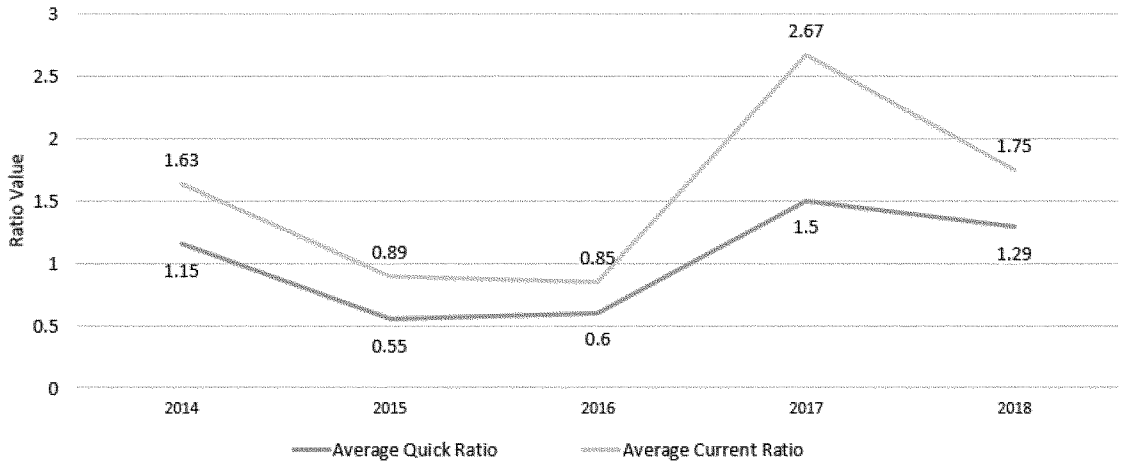
Figure 45: U.S. Miners Debt Ratio



Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 5 — 20 Respondents

Average quick ratios and average current ratios indicate whether, on average, companies are able to cover near term liabilities in the short term. Values greater than one indicate that a company's assets can cover their near term liabilities, but it does not ensure that a company is able to cover long term liabilities with assets (*see* Figure 46).

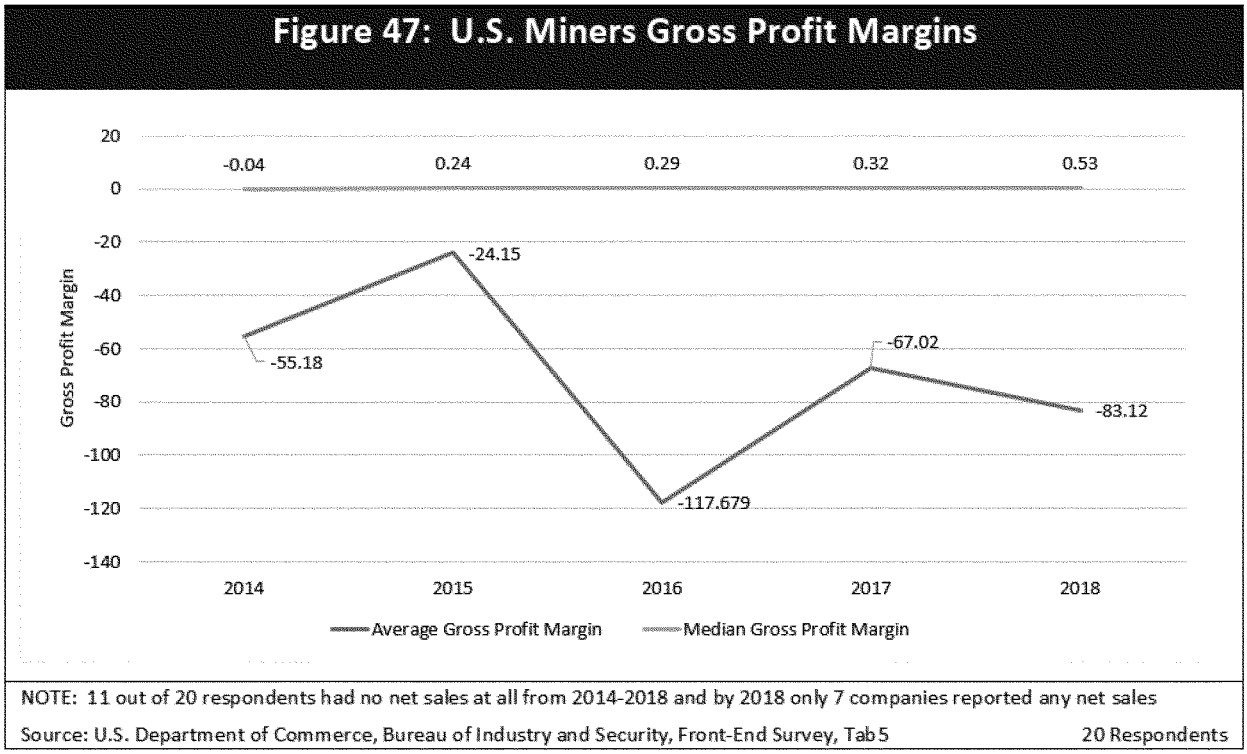
Figure 46: U.S. Mining Companies Quick and Current Ratios

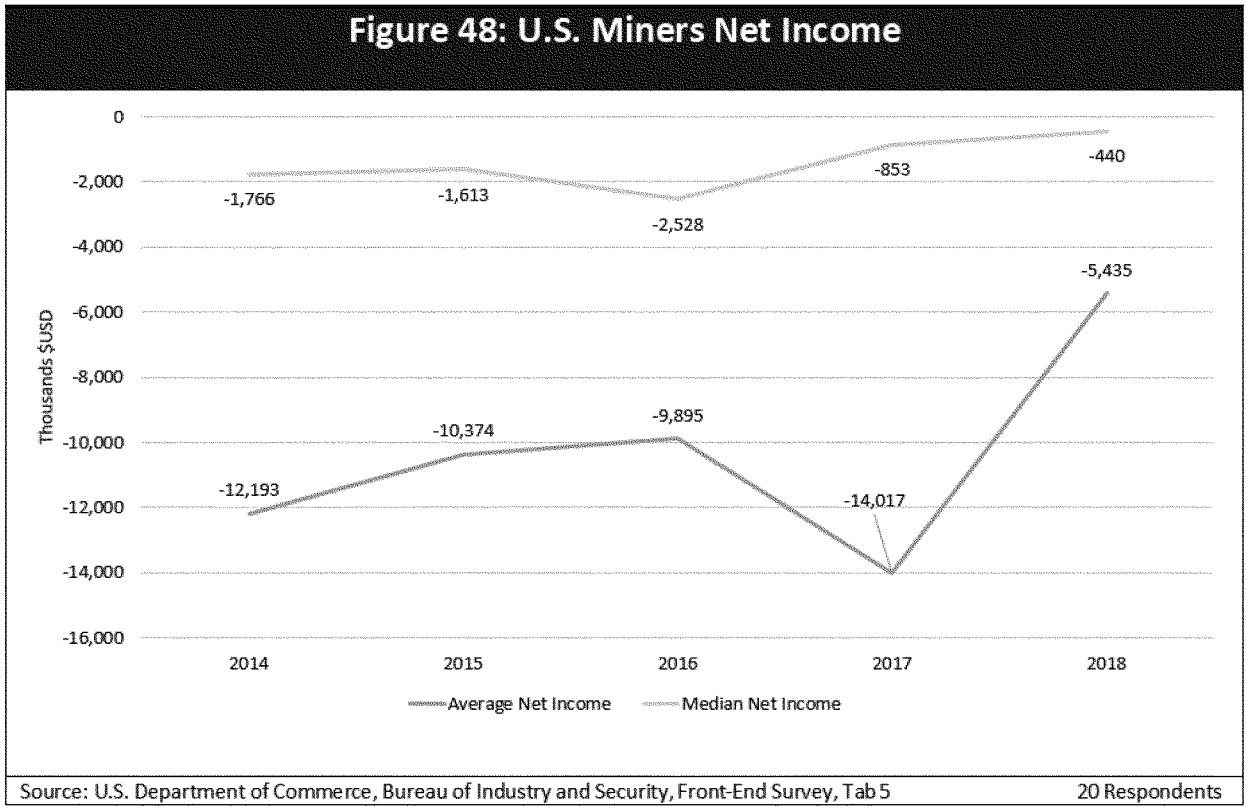


[TEXT REDACTED]

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 5 — 19 Respondents

Uranium miners have also suffered from low profit margins (*see* Figure 47) and persistently negative net income (*see* Figure 48). The average gross profit margin for the surveyed companies is strongly negative and when paired with the average net income it shows that miners are losing money on operations at an alarming rate.





Both gross profit margin and net income should be interpreted in the context of the few actively operating companies currently suffering the largest losses. Many of the idled companies reported negative net income due to the cost of maintaining permits and machinery. [TEXT REDACTED] [135] This is in fact the case with other miners as well. In order to fulfill contracts, miners have purchased off the spot market to mitigate the financial losses from producing themselves or fulfilling contracts with their

[135] [TEXT REDACTED].

inventories. [TEXT REDACTED] [136] To this end financial statements do not fully capture the cost cutting implementations being made to remain solvent.

Without a decrease in imports and an increase in prices and demand, mining operations will continue to have surmounting financial struggles. If current market conditions continue to exist, mining companies will begin to exit the market and this vital component of the fuel cycle will be lost.

Uranium Converters

There is only one location in the U.S. that has conversion services. This is an integral point in the fuel cycle, yet it is not immune to financial struggles faced by the miners. [TEXT REDACTED] [137]

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

[136] [TEXT REDACTED].

[137] [TEXT REDACTED].

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

Uranium Enrichers

Urenco USA and Centrus Energy are the only uranium enrichers in the U.S., though only Urenco currently operates in that capacity. [TEXT REDACTED] [138]

[138] [TEXT REDACTED].

[TEXT REDACTED]

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

Enrichment is a key part of the nuclear fuel cycle and these two companies represent the entire U.S. capability to commercially enrich nuclear material. Retaining their vital capabilities is necessary to preserve the domestic fuel cycle, as their financial struggles are driven by the current state of the market.

Fuel Fabricators

The fuel fabricators are largely unaffected by financial struggles in other sectors of the industry. Debt ratios show that most cover the majority of their liabilities (*see* Figure 53).

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[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

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[TEXT REDACTED]
[TEXT REDACTED]
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[TEXT REDACTED] [TEXT REDACTED]

[TEXT REDACTED] Over the longer term, the fuel fabricators are concerned that Russia and Chinese SOEs will sell fabricated fuel directly to the nuclear electric power operators, bypassing the need for U.S. domestic fuel fabricators.

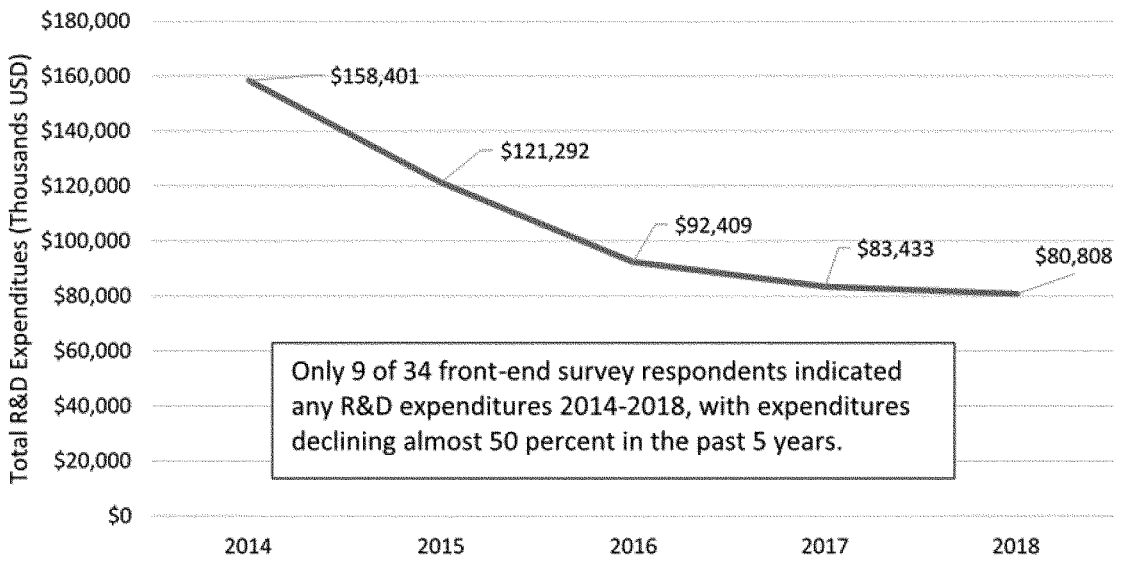
[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

8. Research and Development Expenditures

Research and development (R&D) is critical to the future competitiveness of the U.S. uranium industry. Across all sectors, from initial mining through final fuel fabrication, consistent R&D expenditures are needed to devise and implement new manufacturing techniques and improved processes. R&D is particularly critical for uranium enrichment and fuel fabrication, as their uranium products are highly engineered and tailored to individual utility customers' specifications.

The oversupplied global uranium market has impacted the industry's ability to support continued R&D and expenditures have been consistently declining over the 2014 to 2018 period (*see* Figure 56).

Figure 56: Total Front-End U.S. Uranium Industry R&D Expenditures, 2014-2018



Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 7 — 34 Respondents

[TEXT REDACTED] Other mining company respondents, including both existing mining companies and those owning deposits for future development, have limited available working capital. These firms prioritize the maintenance of existing sites and development costs (particularly permitting) for future sites, and have no

ability to spend on R&D. The lack of R&D spending by mining companies, caused by poor uranium market conditions, will negatively affect their long-term competitiveness. These firms will not be able to develop new production methods and techniques- for example, [TEXT REDACTED]

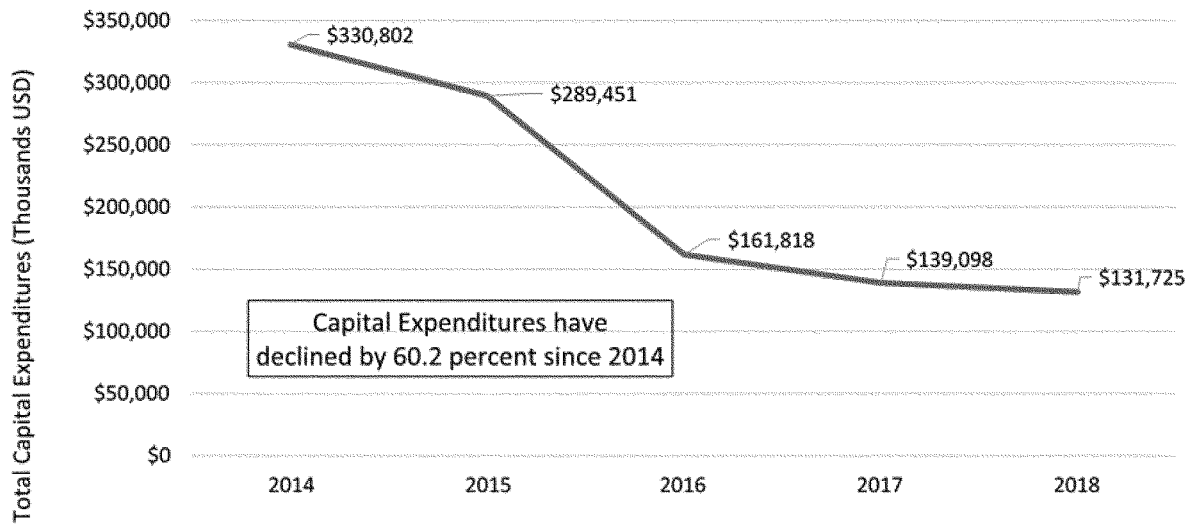
[TEXT REDACTED] noted that poor economic conditions caused them to significantly cut R&D expenditures. [TEXT REDACTED]

Although U.S. uranium firms are currently able to fund a small amount of R&D, their limited ability to invest in this area will constrain future growth. Depressed uranium prices, caused by artificially low-priced imports, oblige U.S. firms to cut costs wherever possible, particularly in R&D. Low R&D expenditures will, in turn, inhibit U.S. firms from being competitive on a global level.

9. Capital Expenditures

All sectors of the U.S. uranium industry are capital-intensive. Mining companies hold significant capital investments in their deposits and the associated mining equipment; converters and enrichers hold significant investments in their proprietary conversion and enrichment processes; and fuel fabricators also have significant investments in the equipment and facilities needed to make fuel assemblies. Capital investment in the industry, however, has been hampered by poor uranium market conditions, with capital expenditures across the U.S. uranium industry falling by 60.2 percent from $330.8 million in 2014 to $131.7 million in 2018 (*see* Figure 57).

Figure 57: Total Front-End U.S. Uranium Industry Capital Expenditures, 2014-2018



Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 6a 18 Respondents

Global uranium market conditions have had various impacts on different stages of the fuel cycle. [TEXT REDACTED]

[TEXT REDACTED] Both of these firms are representative of the effect of global import trends on U.S. uranium mining as well as U.S. uranium enrichment. Excess global supply of uranium concentrate, as well as excess global capacity to produce enriched material, places pressure on domestic U.S. producers, thus impacting their ability to invest in expanding productive capacity.

In contrast, however, U.S. fuel fabricators reported an increase in capital expenditures over the 2014 to 2018 period. [TEXT REDACTED] These increases indicate the comparatively strong state of the U.S. fuel fabrication sector. Due to prohibitive tariffs and reporting requirements associated with imported fuel assemblies, U.S. nuclear power generators opt to have their assemblies produced in the United States. U.S. fuel fabricators do not experience the same market pressures as do U.S. producers of uranium concentrate and enriched uranium.

However, should demand for nuclear fuel in the U.S. drop due to continued or accelerated reactor retirements, these firms will likely experience financial pressures that will force them to cut capital expenditures. In addition, long-term Russian and Chinese efforts to sell fuel directly to U.S. nuclear electric power utilities will also negatively impact domestic fuel fabricators.

A viable U.S. uranium industry must be able to make adequate capital expenditures to maintain existing production levels and prepare for future expansion. However, in the current depressed uranium market, it is not possible for U.S. firms to do so.

C. Trade Actions: Anti-Dumping and Countervailing Duties

The U.S. Government has taken action against artificially low-priced uranium imports. Several anti-dumping investigations conducted by the

Department and the U.S. International Trade Commission (USITC) affirm that many sources of imported uranium have engaged in dumping and other anti-competitive practices to the detriment of U.S. producers. Figure 58 lists USITC investigations into uranium imports since 1991:

U.S.S.R. Less Than Fair Value Sales

FIGURE 58: U.S. INTERNATIONAL TRADE COMMISSION URANIUM CASES SINCE 1991

Country	Date	Finding
Union of Soviet Socialist Republics (U.S.S.R.)	December 23, 1991	Affirmative.
Russia, Belarus, Ukraine, Moldova, Georgia, Armenia, Azerbaijan, Kazakhstan, Kyrgyzstan, Uzbekistan, Tajikistan, Turkmenistan*.	June 3, 1992	Affirmative.
Tajikistan	July 8, 1993	Negative.
Ukraine	July 8, 1993	Affirmative.
Kazakhstan	July 13, 1999	Negative.
Ukraine	August 22, 2000	Negative.
Russia (First Review of 1992 Determination)	August 22, 2000	Affirmative.
France, Germany, the Netherlands, and the United Kingdom	February 4, 2002	Affirmative.
Russia (Second Review of 1992 Determination)	August 2006	Affirmative.
France (First Review of 2002 Determination)	December 2007	Affirmative.
Russia (Third Review of 1992 Determination)	February 2012	Affirmative.
Russia (Fourth Review of 1992 Determination)	September 2017	Affirmative.
France (Third Review of 2002 Determination)	November 2018	Negative.

*The cases determined on June 3, 1992 were a continuation of the December 23, 1991 anti-dumping case against the U.S.S.R. As the U.S.S.R. was dissolved December 25, 1991; the International Trade Commission opened cases against the twelve former Soviet republics.
Source: USITC.

In December 1991, the Department and the USITC determined that imports of uranium from the U.S.S.R., including natural and enriched uranium, were sold in the U.S. at less than fair value and threatened material injury to the U.S. uranium industry.[139] Following the dissolution of the U.S.S.R. in the same month, the single investigation was then transformed into twelve separate investigations, which covered most former Soviet republics.[140] In June 1992, the Department and USITC found that uranium imports from each of these republics were sold at less than fair value and threatened to materially injure U.S. producers. Subsequently, six of the republics—Russia, Kazakhstan, Kyrgyzstan, Tajikistan, Ukraine, and Uzbekistan—signed agreements with the U.S. government to suspend the underlying antidumping duty investigations. These suspension agreements permitted the countries in question to import defined amounts of uranium into the United States, thereby avoiding the imposition of antidumping duty orders and the resulting duties.

After 1992, most of the antidumping duty orders and suspension agreements had been terminated pursuant to proceedings; the Department and USITC determined that imports of uranium from most of the Soviet republics were not materially injuring, or threatening to materially injure, U.S. industry. By 2000, only the agreement with Russia remained in force. In its 2000, 2006, 2012, and 2017 reviews of the Russian Suspension Agreement (RSA), USITC reaffirmed that imports of Russian uranium beyond the quantities permitted in the RSA would lead to a ''recurrence of material injury'' to the U.S. uranium industry.[141]

France, Germany, the Netherlands, and the United Kingdom

In December 2000, United States Enrichment Corporation (now Centrus Energy Corp.) filed a petition with the Department and USITC concerning imports of low-enriched uranium (LEU) from France, Germany, the Netherlands, and the United Kingdom. In February 2002, USITC concluded that LEU imports from these countries were sold inside the U.S. at less than fair value and had a ''significant adverse impact'' on domestic U.S. LEU production.[142] Commerce accordingly imposed countervailing duties on LEU imports from all of the above countries as well as anti-dumping duties on French imports.

Subsequent actions by the Department revoked all of the countervailing duties by May 2007. However, the anti-dumping duties on French LEU remained in place. Further USITC reviews in December 2007 and December 2013 affirmed that the anti-dumping duties were needed to deter less than fair value sales of French LEU. Following a final review in November 2018 and a lack of domestic interested parties, the Department revoked the anti-dumping duties on French LEU on March 15, 2019.[143]

Prior actions by USITC and the Department support the U.S. Government's broader concern about the viability of the domestic uranium industry as well as the clear impact of anticompetitive practices by non-U.S. suppliers on U.S. producers.

D. Displacement of Domestic Uranium by Excessive Quantities of Imports Has the Serious Effect of Weakening Our Internal Economy

1. U.S. Production Is Well Below Demand and Utilization Rates Are Well Below Economically Viable Levels

Based on the Department's 2019 survey data, U.S. uranium production is well below U.S. demand even though adequate capabilities and resources exist. In 2018, U.S. utility requirements were about 51.9 million pounds of U308 to run all reactors at full capacity, and total U.S. licensed and operating uranium production capacity was about 226 million pounds of U308. However, U.S. uranium production in 2018 was

[139] U.S. International Trade Commission. *Uranium from the U.S.S.R.'' Investigation No. 731–TA–539 (Preliminary).* (Washington, DC: 1991). *https://www.usitc.gov/publications/701_731/pub2471.pdf.*

[140] ''Uranium from Russia: Investigation No. 731–TA–539–C (Fourth Review).'' USITC. (September 2017).

[141] Ibid. 1.

[142] U.S. International Trade Commission. *Low Enriched Uranium from France, Germany, the Netherlands, and the United Kingdom,* 18. Investigation Nos. 701–TA–409–412 and 731–TA–909, Final. (Washington, DC: 2002). *https://www.usitc.gov/publications/701_731/pub3486.pdf.*

[143] Low-Enriched Uranium from France: Final Results of Sunset Review and Revocation of Antidumping Duty Order, **Federal Register** 84 FR 9493, (March 15, 2019), *https://www.federalregister.gov/documents/2019/03/15/2019-04882/low-enriched-uranium-from-france-final-results-of-sunset-review-and-revocation-of-antidumping-duty.*

less than two million pounds of U308 (*see* Figure 59).

Figure 59: U.S. Uranium-related Production and Use

Current State of Uranium Ore & ISR-Mines (as of 2018)	
Active Nuclear Reactors in the U.S.	98
Annual U308 Needed to Run All Reactors at Full Capacity	51,890,163 Pounds
Total U308 Production in U.S.	709,806 Pounds
Total Operating U308 Production Capacity in U.S.	225,646,340 Pounds
Total Licensed U308 Production Capacity in U.S.	237,448,340 Pounds
Total U308 Production in U.S.	723,000 Pounds[1]
Total Operating U308 Production Capacity in U.S.	45,500,750 Pounds[1]
Total Licensed U308 Production Capacity in U.S.	49,001,000 Pounds[1]

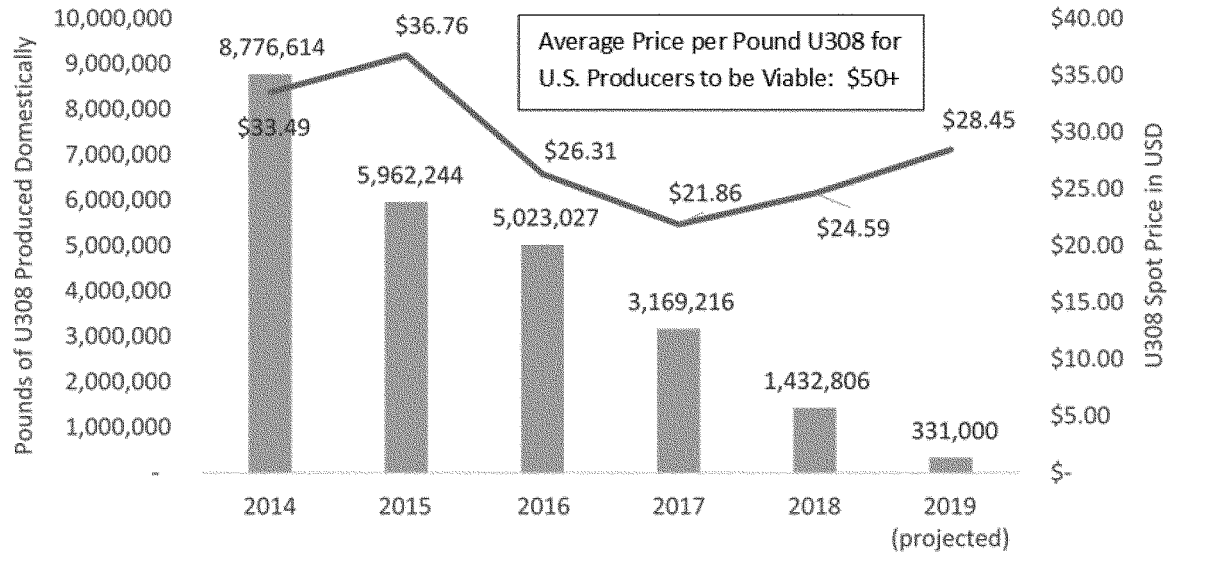
[1] includes mined and milled products produced by millers only

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 3a, 4a
Nuclear Power Operator Sector Survey, Tab 3a

The average projected utility requirements of U308 for 2019 to 2025 are 280 million pounds. These variations are due to the 2019 decommissioning of two reactors with potentially eleven more reactors closing by 2025. In addition, four new reactors will be coming online by 2020.[144] Despite this demand, the prognosis for the U.S. uranium industry worsens with only 331,000 pounds of U308 production in 2019, which is 53 percent lower than 2018 and is only six percent of 2014 levels.

This decline is largely due to unfavorable market conditions. For example, the 25 mines that are currently idled/in standby said the primary factor prohibiting restart is low uranium spot prices. An additional two mines are completely shut down due to low uranium spot prices. Total production by U.S. mines and mills of uranium ore and concentrates continues to decrease drastically as global uranium market conditions continue to decline (*see* Figure 60).

Figure 60: U.S. Production and Global Spot Price of U308



Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 4a; Federal Reserve Bank of St. Louis

6 respondents

[144] U.S. Nuclear Regulatory Commission.

The low uranium spot price also contributes to utilization rates that are well below economically viable levels. According to BIS survey data, front-end U.S. uranium producers indicated widely varying capacity utilization rates needed to remain profitable, with the lowest recorded at 25 percent, and the highest recorded at 100 percent. The industry average capacity utilization rate U.S. uranium producers need to remain profitable is roughly 56 percent. In the recent past, the utilization rate has been 3/10 of one percent (0.3 percent) of licensed/operating capacity. The industry cannot sustain at these unprofitable rates.

However, once market conditions improve, U.S. uranium producers can justify restarting operations and/or starting new operations. Most U.S. uranium miners and millers are unable to produce at a viable level at the current low spot prices, but are ready to produce when economic conditions are more favorable (*see* Figure 61).

Figure 61: Current State of the U.S. Uranium Miners

	Under Development	Operating	Standby /Idle	Total
Underground	9	0	30	**39**
Open Pit /Surface	0	0	2	**2**
In-Situ Recovery	5	5	7	**17**
Total	**14**	**5**	**39**	**58**

- Of the 14 mines "under development," 6 are "permitted to operate" and 2 are ready to start operations.
- Of the 39 mines in "standby/idle," 28 are "permitted to operate" and 4 are ready to start operations.
- Of the 5 mines "operating," one (1) is expected to enter "standby/idle" (2019-2023).

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 3a

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Of the uranium mining projects in idling/standby status, many indicated that it would take about one year to restart production, with a maximum time period estimated at four years and the minimum estimated at 30 days. The cost to fully restart production varied more widely with the maximum being $100 million, the minimum being $200 thousand, and the average being $12.8 million.

Furthermore, uranium deposits in the U.S. are vast (approximately 1.2 billion pounds of U308) and can be extracted when the price reaches a level for production to be economically viable (*see* Figures 62 and 63).

Figure 62: U.S. Uranium-related Production and Use

Current State of Uranium Ore & ISR-Mines (as of 2018)	
Active Nuclear Reactors in the U.S.	98
Annual U308 Needed to Run All Reactors at Full Capacity	51,890,163 Pounds
Total U308 Production in U.S.	709,806 Pounds
Total Operating U308 Production Capacity in U.S.	225,646,340 Pounds
Total Licensed U308 Production Capacity in U.S.	237,448,340 Pounds
Total U308 Production in U.S.	723,000 Pounds[1]
Total Operating U308 Production Capacity in U.S.	45,500,750 Pounds[1]
Total Licensed U308 Production Capacity in U.S.	49,001,000 Pounds[1]

Future State (Projected beyond 2019)	
Total U3O8 Production in U.S. up to $30/pound of U308	9,108,000 pounds
Total U3O8 Production in U.S. up to $50/pound of U308	340,103,597 pounds
Total Undeveloped Resources in U.S. (measured +inferred)	1,126,337,293 pounds

[1] includes mined and milled products produced by millers only

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 3a, 4a; Nuclear Power Operator Survey, Tab 3a

58 Respondents

Figure 63: Undeveloped U.S. Uranium Resources

State	Measured Resources	Inferred Resources	Avg. Est. Production Cost	Effected FTEs
Arizona	19,434,000	21,850,000	[TEXT REDACTED]	[TEXT REDACTED]
Colorado	32,820,171	67,416,514	[TEXT REDACTED]	[TEXT REDACTED]
Nebraska	15,300,000	3,000,000	[TEXT REDACTED]	[TEXT REDACTED]
New Mexico	48,164,000	314,926,000	[TEXT REDACTED]	[TEXT REDACTED]
South Dakota	17,999,000	818,000	[TEXT REDACTED]	[TEXT REDACTED]
Texas	9,072,000	112,226,000	[TEXT REDACTED]	[TEXT REDACTED]
Utah	22,128,640	14,778,265	[TEXT REDACTED]	[TEXT REDACTED]
Virginia	119,000,000	--	[TEXT REDACTED]	[TEXT REDACTED]
Wyoming	273,278,887	125,125,816	[TEXT REDACTED]	[TEXT REDACTED]
U.S. Total	**557,196,698**	**660,140,595**	[TEXT REDACTED]	[TEXT REDACTED]

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Tab 3b

15 respondents

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2. Domestic Uranium Production Is Severely Weakened and Concentrated

As the U.S. uranium industry contracts and shuts down due to the imports adversely impacting its economic welfare and viability, domestic uranium production is severely weakened and concentrated. Since imports as a percentage of U.S. utilities' annual uranium consumption have increased to upwards of 94 percent, U.S. production of uranium concentrate has declined from 12.3 million pounds in 1989 to just 331,000 pounds of uranium concentrate projected for 2019. Consequently, the mills which process uranium ore are near to shuttering operations.

[TEXT REDACTED]

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

3. Reduction of Uranium Production Facilities Limits Capacity Available for a National Emergency and Threatens To Impair National Security

Key factors in this investigation include growth requirements of domestic industries to meet national defense requirements; however, reduction of uranium production facilities limits the capacity available in the event of a national emergency. The United States cannot be subject and should not be subject to foreign dependence in the face of potential uranium needs in an emergency scenario. The decline of the U.S. uranium production industry limits availability and puts the U.S. at risk, impairing national security. On the miners side, sales and export data show that U.S. producers are selling more product than they are producing, indicating that contracts are being fulfilled with either inventory, spot market purchases, or other. U.S. mines have resorted to buying spot market uranium in order to fulfill contracts since it is cheaper than producing themselves.

[TEXT REDACTED]					
[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]
[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]
[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]
[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]
[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]	[TEXT REDACTED]
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[TEXT REDACTED] [TEXT REDACTED]					

The U.S. uranium industry's low production levels force U.S. nuclear power generators into heavy dependence on foreign uranium supplies. Of the 98 active U.S. nuclear reactors, only four have annual requirements less than 331,000 pounds U3O8 per year, which is the total U.S.

production expected for 2019 (*see* Figure 65).

Projected 2019 U.S. uranium production would be sufficient to fuel only one of these reactors. [TEXT REDACTED] Low U.S. production levels denote that a sudden loss of access to foreign uranium supplies has the potential to severely disrupt the nuclear power plants that provide almost one-fifth of the nation's electricity.

[TEXT REDACTED] Therefore, a remedy to resolve the inhibiting factors to production must be implemented so that U.S. miners are once again reliable suppliers of uranium, and with additional U.S. capability to convert and enrich the mined uranium, U.S. utilities are able to fulfill their need of domestic uranium for national security or national emergency use.

As previously discussed, the stockpile maintained by DOE is anticipated to satisfy needs for LEU and HEU through 2041 and 2060 respectively. However, U.S. nuclear electric power utilities only maintain enough inventory of uranium to fuel their reactors for an average of [TEXT REDACTED] (*see* Figure 66). The compounded effects of both minimal inventory and minimal U.S. production highlights the national security threat imposed by U.S. nuclear electric utilities' near complete dependence on imports of uranium to fuel their reactors. In the event of a supply disruption, U.S. utilities' would be unable to supply the 19 percent of U.S. electricity consumption they usually provide after [TEXT REDACTED]. The continued loss in U.S. production capabilities ensures that a disruption in supply to the nation's 98 reactors would be catastrophic to U.S. critical infrastructure.

[TEXT REDACTED]
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[TEXT REDACTED] [TEXT REDACTED]

E. Uranium Market Distortion by State-Owned Enterprises Is a Circumstance That Contributes to the Weakening of the Domestic Economy

1. Excess Russian, Kazakh, and Uzbek Production Adversely Affects Global Markets and Creates a Dangerous U.S. Dependence on Uranium From These Countries

Although global uranium production increased by 42 percent between 2008 and 2016, the subsequent supply glut following the Fukushima disaster and reactor retirements has begun to affect production.[145] As the potential for new reactor construction increased, new mines came online to meet potential demand. In 2008, the world's uranium mines produced enough uranium to fulfill 70 percent of existing world demand. By 2016, global uranium production filled 98 percent of world demand.

However, the increasing pace of reactor retirements, cancellation of proposed new reactors, and excess supply caused by the shutdown of German and Japanese reactors all impacted the global uranium market. Accordingly, between 2016 and 2017, global uranium production dropped by 4.7 percent—remaining production could satisfy 93 percent of 2017 demand. As more reactors come online in certain regions, particularly in Asia, the Middle East, and Africa, global demand is expected to grow once more.

By 2025, the International Atomic Energy Agency estimates that global uranium demand could be as high as 68,920 metric tons—a 10 percent increase on 2016 levels. However, current poor market conditions, exacerbated by artificially low-priced SOE producers, have forced many producers in the U.S. and other countries to idle production or close mines entirely. U.S. and other market producers may therefore not be present in the market to take advantage of higher future demand.

Thus, while U.S. production declined by 16 percent between 2016 and 2017, Russian and Kazakh production declined only by 5.1 and 2.9 percent respectively (*see* Figure 67). Uzbek production remained constant. Even Canada and Australia, which have historically produced more than the U.S., cut their production to a greater degree than did Russia, Kazakhstan, and Uzbekistan.

FIGURE 67: CHANGES IN URANIUM PRODUCTION, 2016–2017

Country	2016 Production (metric tons uranium)	2017 Production (metric tons uranium)	Change in production (percentage)
United States	1,125	940	−16.4
Canada	14,039	13,116	−6.55
Australia	6,315	5,882	−6.86
Russia	3,004	2,917	−2.89
Kazakhstan	24,586	23,321	−5.14
Uzbekistan	2404	2404	0
China	1616	1885	16.6

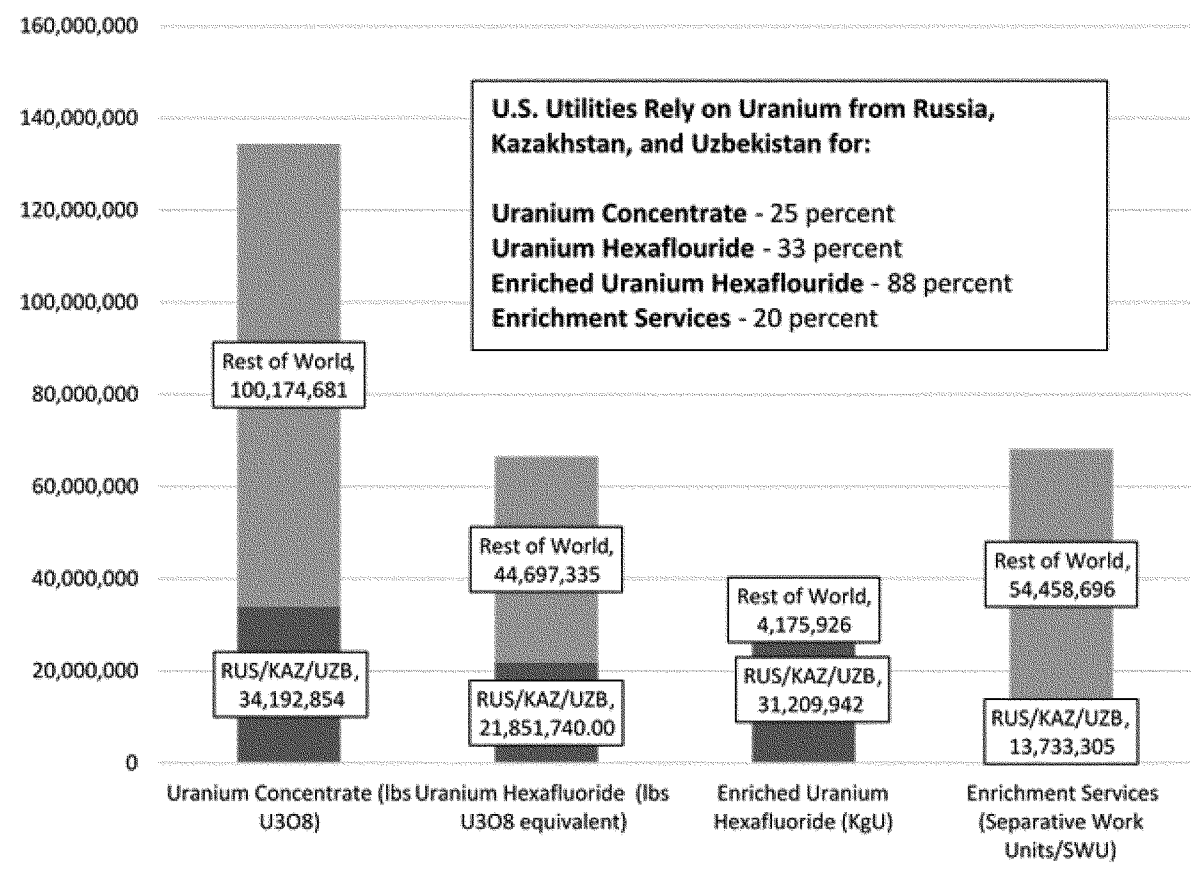
Source: World Nuclear Association, March 2019, 2018 data has not been released.

[145] "World Uranium Mining Production." World Nuclear Association. *http://www.world-nuclear.org/information-library/nuclear-fuel-cycle/mining-of-uranium/world-uranium-mining-production.aspx.*

Russia's Rosatom, Kazakhstan's Kazatomprom, and Uzbekistan's Navoi are able to maintain higher production levels than most producers despite unfavorable global markets because they are state-owned enterprises. Should global market trends persist and uranium prices remain low, U.S. producers will not be able to compete with price-insensitive production in these countries.

As U.S. and other market production declines and Russian, Kazakh, and Uzbek production remains stable, U.S. utilities are purchasing increasing amounts of uranium products from these countries. Figure 68 shows the extent to which U.S. utilities rely on Russia, Kazakhstan, and Uzbekistan for a significant share of their uranium needs.

Figure 68: U.S. Utility Purchases of Uranium Products from Russia, Kazakhstan, and Uzbekistan, 2014-2018

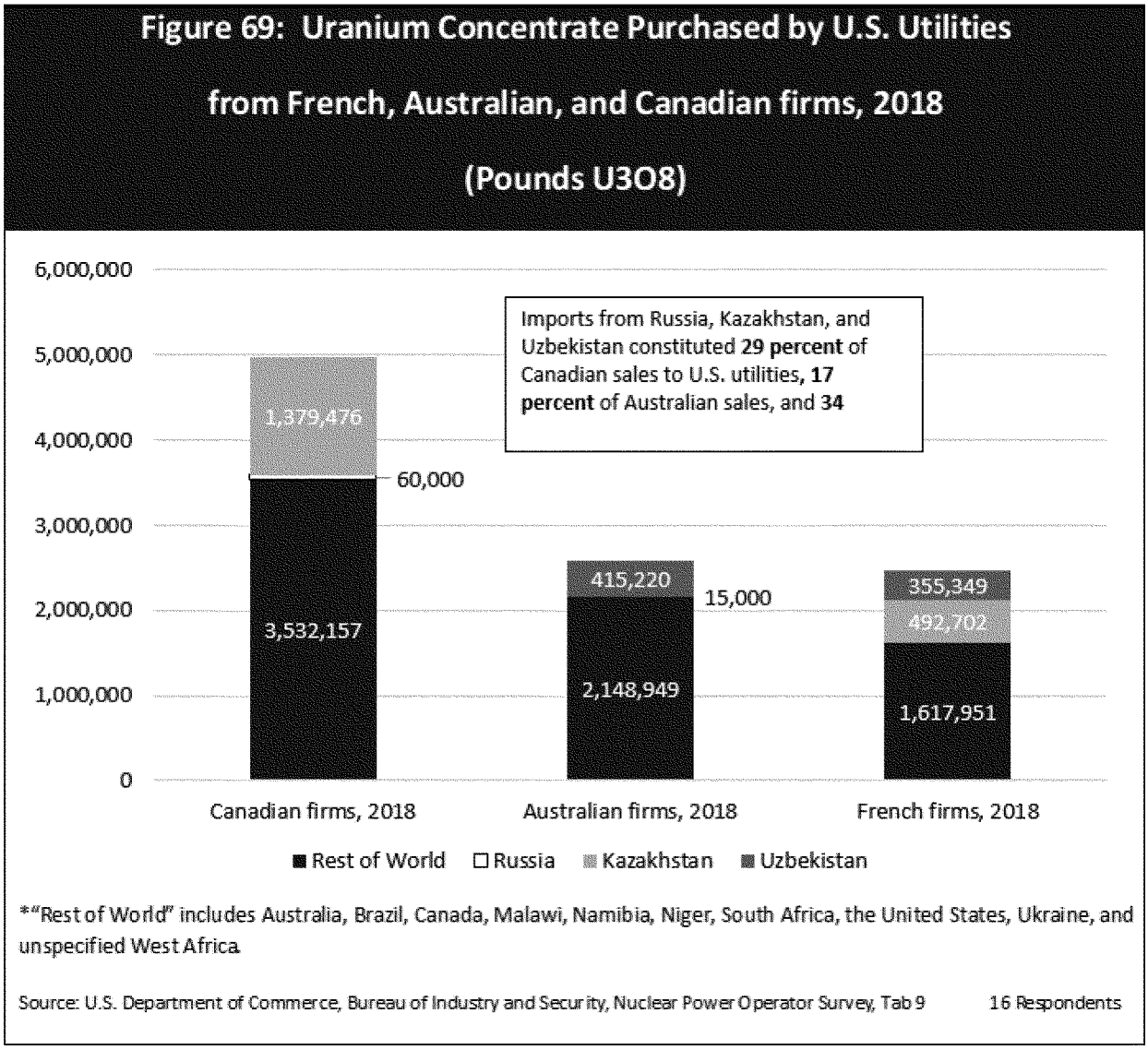


Source: U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power Operator Survey, Tab 9 16 Respondents

Between 2014 and 2018, U.S. utilities relied on material from Russia, Kazakhstan, and Uzbekistan for 25 percent of their uranium concentrate, 32 percent of their uranium hexafluoride, 14 percent of their conversion services, and 20 percent of their enrichment services. Consequently, U.S. utilities are dependent on imports from these countries to maintain normal operations at their nuclear generators. As U.S. and other market producers cut or cease uranium production due to unfavorable market conditions, it is likely that U.S. utilities will increase purchases of uranium from price-insensitive Russian, Kazakh, and Uzbek producers.

Continued high levels of Russian, Kazakh, and Uzbek production is also affecting U.S. allies. As described in Chapter VI, Canadian and Australian producers have had to idle production at their own mines due to poor market conditions. Furthermore, to fulfill contracts with U.S. utilities, Canadian, Australian, and French producers have procured material from state-owned suppliers. Figure 69 shows that Canadian, Australian, and French producers used Russian, Kazakh, and

Uzbek uranium to fulfill many 2018 contracts with U.S. utilities.



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Continued excess production of artificially low-priced uranium by Russia, Kazakhstan, and Uzbekistan will make U.S. and foreign market producers noncompetitive on global markets. As U.S. and other allied nations decrease their production due to poor market conditions, U.S. nuclear power generators will purchase increasing amounts of Russian, Kazakh, and Uzbek uranium to meet their needs.

Dependence on such imports raises a distinct national security concern. The Office of the Director of National Intelligence's 2019 Worldwide Threat Assessment identifies Russia's ambitions to expand its ''global military, commercial, and energy footprint'' as an integral part of its strategy to ''undermine the international order.'' [146]

U.S. utilities' direct dependence on Russian enriched uranium for 20 percent of their annual supply gives the Kremlin significant economic leverage. Moscow exercises further leverage through its *de facto* control of uranium exports from Kazakhstan and Uzbekistan. Although Kazakh and Uzbek SOEs are controlled by their respective governments and not Russia, a significant majority of uranium shipments from Kazakhstan and Uzbekistan transit through Russia on their way to U.S. customers.

[TEXT REDACTED]

[146] Coats, Daniel. Director of National Intelligence, Senate Select Committee on Intelligence. *Statement for the Record: Worldwide Threat Assessment of the US Intelligence Community,* 37. January 29, 2019. *https://www.dni.gov/files/ODNI/documents/2019-ATA-SFR-SSCI.pdf.*

[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

In the event of increased political or potential military tensions, Russia could choose to ban uranium exports to the United States; denying U.S. utilities a significant share of their enriched uranium. Russia further possesses the military means to deny U.S. and U.S.-aligned countries access to Kazakh and Uzbek uranium exported through Russian ports, principally on the Baltic Sea.[147] In either of these circumstances, U.S. utilities would conceivably be denied a significant percentage of their uranium requirements and could face critical fuel shortages.

2. The Increasing Presence of China in the Global Uranium Market Will Further Weaken U.S. and Other Market Uranium Producers

Although China's uranium industry has been developed primarily to serve the country's growing fleet of nuclear reactors, China is increasing its involvement in the global nuclear fuel industry.[148] China's involvement in the global nuclear fuel industry is an outgrowth of its domestic uranium procurement strategy. As China has only limited domestic uranium reserves, it has also acquired interests in uranium deposits outside China. This ''two markets, two resources'' [149] policy has led Chinese firms to acquire significant shares of mines in Kazakhstan and Namibia, with prospective developments in Niger and Canada.[150] China's activity in Namibia is of particular interest.[151] Namibia has two active uranium mines—Husab and Rossing. Chinese firms have a majority stake in Husab and purchased a majority stake in Rossing. However, the Rossing transaction is under review by the Namibia Competition Commission. A Chinese firm does have a 25 percent stake in the Langer Heinrich mine, but that mine was placed in care and maintenance in 2018 and thus cannot be characterized as active. These mines' production costs exceed current global uranium prices, and so cannot support commercial production. However, cost recovery is seemingly not a concern for Chinese-state owned producers.

Between 2014 and 2018, U.S. utilities purchased approximately 347,781 pounds of uranium concentrate, 2.33 million pounds of U3O8 equivalent of conversion services, and 1.4 million separative work units (SWU) of enrichment services—enough to supply 16 average reactors per year—from Chinese producers. U.S. utilities also have contracts with Chinese producers for at least 130,000 SWU between 2019 and 2023, indicating an interest in continued relationships with Chinese producers. U.S. utilities have also contracted with CGN Global Uranium Ltd., the trading arm of Chinese SOE China General Nuclear, for certain uranium purchases. Between 2014 and 2018, U.S. utilities purchased 800,000 pounds of uranium concentrate from CGN Global.

As the bulk of China's uranium concentrate production is consumed by domestic nuclear power generators, most Chinese exports of uranium will likely be in the form of enrichment services. Domestic Chinese enrichment capacity is increasing faster than domestic demand: By 2020, the country's enrichment centrifuges will have a total capacity of 12 million SWU, compared to domestic demand of 9 million SWU.[152] Chinese producers intend to use this excess capacity to increase the country's presence in the nuclear fuels trade. A China National Nuclear Corporation (CNNC) executive remarked in 2013: ''On the basis of securing its domestic supply [of SWU], CNNC will gradually expand its foreign markets and make China's fuel industry internationally competitive.'' [153] China's increasing control of global uranium deposits and its excess enrichment capacity will allow it to further enter the nuclear fuels market and undermine U.S. and other market producers.

3. Increasing Global Excess Uranium Production Will Further Weaken the Internal Economy as U.S. Uranium Producers Will Face Increasing Import Competition

Continued high levels of production by state-owned enterprises in Russia, Kazakhstan, Uzbekistan, and China will place further financial pressure on U.S. uranium producers. U.S. uranium concentrate production, which declined by 94 percent between 2014 and 2018, will be non-existent in the near future as subsidized foreign production continues.

Foreign market producers are not immune from the effects of state-owned producers either. As described in Chapter VI, Canadian and Australian producers have had to idle production at their own mines due to poor market conditions. Furthermore, to fulfill contracts with U.S. utilities, Canadian, Australian, and French producers have procured material from state-owned suppliers.

VIII. Conclusion

A. Determination

Based on these findings, the Secretary of Commerce has concluded that the present quantities and circumstance of uranium imports are ''weakening our internal economy'' and ''threaten to

[147] Since the Russian annexation of Crimea and intervention in eastern Ukraine in 2014, Russia has steadily built up its military assets in the Baltic Sea region. Russia therefore could close Baltic Sea shipping lanes with comparative ease. Oder, Tobias. ''The Dimensions of Russian Sea Denial in the Baltic Sea.'' Center for International Maritime Security, January 04, 2018. *http://cimsec.org/dimensions-russian-sea-denial-baltic-sea/35157*.

[148] ''China's Nuclear Fuel Cycle.'' World Nuclear Association. http://www.world-nuclear.org/information-library/country-profiles/countries-a-f/china-nuclear-fuel-cycle.aspx.

[149] Pascale Massot and Zhan-Ming Chen. ''China and the Global Uranium Market: Prospects for Peaceful Coexistence.'' *The Scientific World Journal,* 2013. *https://www.hindawi.com/journals/tswj/2013/672060/*.

[150] ''China's Nuclear Fuel Cycle.'' World Nuclear Association. *http://www.world-nuclear.org/information-library/country-profiles/countries-a-f/china-nuclear-fuel-cycle.aspx*.

[151] ''Rio Tinto to sell Rössing stake.'' *World Nuclear News,* November 26, 2018. *http://www.world-nuclear-news.org/Articles/Rio-Tinto-to-sell-Rossing-stake.*

[152] Hui Zhang, ''China's Uranium Enrichment Capacity: Rapid Expansion to Meet Commercial Needs'', (Cambridge: Harvard Kennedy School, 2015), 32.

[153] Ibid., 34.

impair the national security'' as defined in Section 232. An economically viable and secure supply of U.S.-sourced uranium is required for national defense needs. International obligations, including agreements with foreign partners under Section 123 of the Atomic Energy Act of 1954, govern the use of most imported uranium and generally restrict it to peaceful, non-explosive uses. As a result, uranium used for military purposes must generally be domestically produced from mining through the fuel fabrication process. Furthermore, the predictable maintenance and support of U.S. critical infrastructure, especially the electric power grid, depends on a diverse supply of uranium, which includes U.S.-sourced uranium products and services.

The Secretary further recognizes that the U.S. uranium industry's financial and production posture has significantly deteriorated since the Department's 1989 Report. That investigation noted that U.S. nuclear power utilities imported 51.1 percent of their uranium requirements in 1987. By 2018, imports had increased to 93.3 percent of those utilities' annual requirements. Based on comprehensive 2019 industry data provided by U.S. uranium producers and U.S. nuclear electric power utilities to the Department in response to a mandatory survey, U.S. utilities' usage of U.S. mined uranium has dropped to nearly zero. [TEXT REDACTED] Based on the current and projected state of the U.S. uranium industry, the Department has concluded that the U.S. uranium industry is unable to satisfy existing or future national security needs or respond to a national security emergency requiring a significant increase in domestic uranium production.

Absent immediate action, closures of the few remaining U.S. uranium mining, milling, and conversion facilities are anticipated within the next few years. Further decreases in U.S. uranium production and capacity, including domestic fuel fabrication, will cause even higher levels of U.S. dependence on imports, especially from Russia, Kazakhstan, Uzbekistan, and China. Increased imports from SOEs in those countries, and in particular Russia and China, which the 2017 National Security Strategy noted present a direct challenge to U.S. influence, are detrimental to the national security.[154] The high risk of loss of the remaining U.S. domestic uranium industry, if the present excessive level of imports continue, threatens to impair the national security as defined by Section 232.

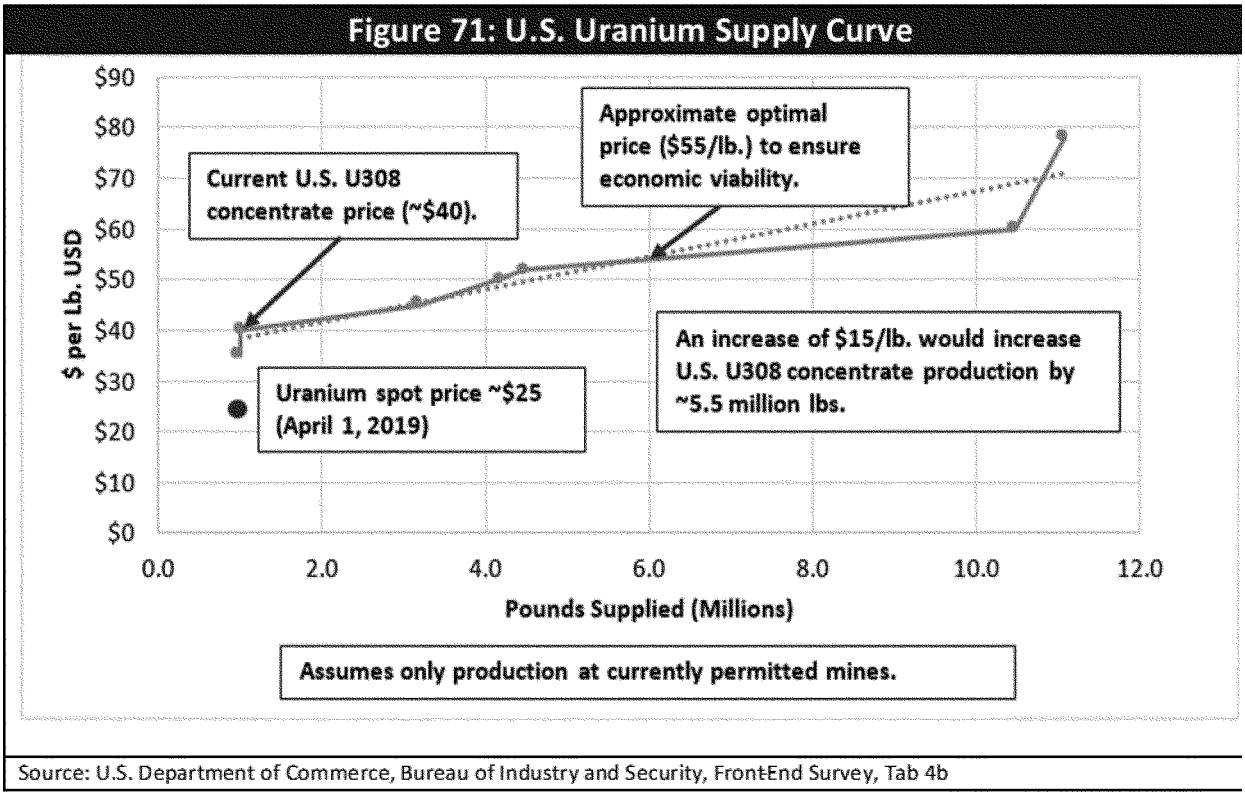
The Secretary has determined that to remove the threat of impairment to national security, it is necessary to reduce imports of uranium to a level that enables U.S. uranium producers to return to an economically competitive and financially viable position. This will allow the industry to sustain production capacity, hire and maintain a skilled workforce, make needed capital expenditures, and perform necessary research and development activities. A modest reduction of uranium imports will allow for the revival of U.S. uranium mining and milling, the restart of the sole U.S. uranium converter, and a reduction in import challenges to fuel fabricators, while also recognizing the market and pricing challenges confronting the U.S. nuclear power utilities.

Recommendation

Due to the threat to the national security, as defined in Section 232, from excessive uranium imports, the Secretary recommends that the President take immediate action by adjusting the level of these imports through implementation of an import waiver to achieve a phased-in reduction of uranium imports. The reduction in imports of uranium should be sufficient to enable U.S. producers to recapture and sustain a market share of U.S. uranium consumption that will allow for financial viability, and enable the maintenance of a skilled workforce and the production capacity and uranium output needed for national defense and critical infrastructure requirements. The reduction imposed should be sufficient to enable U.S. producers to eventually supply 25 percent of U.S. utilities' uranium needs based on 2018 U.S. U308 concentrate annual consumption requirements.

Based on the survey responses, the Department has determined that U.S. uranium producers require an amount equivalent to 25 percent of U.S. nuclear power utilities' 2018 annual U308 concentrate consumption to ensure financial viability. Based on the Department's analysis, if U.S.-mined uranium supplied 25 percent of U.S. nuclear power utilities' annual U308 concentrate consumption, U.S. uranium prices will increase to approximately $55 per pound (*see* Figure 71). The current spot price is low due to distortions from SOEs.

[154] U.S. White House Office. *National Security Strategy of the United States of America.* (Washington, DC: 2017), 2 *https://www.whitehouse.gov/wp-content/uploads/2017/12/NSS-Final-12-18-2017-0905-2.pdf.*



Source: U.S. Department of Commerce, Bureau of Industry and Security, FrontEnd Survey, Tab 4b

The $55 per pound price will increase mine capacity to the point where U.S. uranium mines can supply approximately 6 million pounds of uranium concentrate per year, which is approximately 25 percent of U.S. nuclear power utilities' consumption for U308 concentrate in any given year.

The Secretary recommends that the import reduction be phased in over a five-year period. This will allow U.S. uranium mines, mills, and converters to reopen or expand closed or idled facilities; hire, train and maintain a skilled workforce; and make necessary investments in new capacity. This phased-in approach will also allow U.S. nuclear power utilities time to adjust and diversify their fuel procurement contracts to reintroduce U.S. uranium into their supply chains.

The Secretary recommends that either a targeted or global quota be used to adjust the level of imports and that such quota should be in effect for a duration sufficient to allow the necessary time needed to stabilize and revitalize the U.S. uranium industry. According to survey responses, the average time to restart an idle uranium production facility is two to five years, and several additional years are needed to add new capacity. Market certainty, which can be provided by long-term contracts with U.S. nuclear power utilities, is needed to build cash flow, pay down debt, and raise capital for site modernization; workforce recruitment; and to conduct environmental and regulatory reviews.

Option 1—Targeted Zero Quota

This targeted zero quota option would prohibit imports of uranium from Kazakhstan, Uzbekistan, and China (the ''SOE countries'') to enable U.S. uranium producers to supply approximately 25 percent of U.S. nuclear power utility consumption. A U.S. nuclear power utility or other domestic user would be eligible for a waiver that allows the import of uranium from the SOE countries, with any import of uranium from Russia subject to the Russian Suspension Agreement, after such utility or user files appropriate documentation with the Department. In the case of a U.S. nuclear power utility, the documentation must show that such utility has a contract or contracts to purchase for their consumption on an annual basis not less than the percentage of U.S. produced uranium U308 concentrate shown in the phase-in table below.

PERCENT OF ANNUAL U308 CONCENTRATE CONSUMPTION REQUIRED TO BE SOURCED FROM THE U.S.

Year	2020	2021	2022	2023	2024 and beyond
Percent of Annual U308 Concentrate Consumption Required to be Sourced from the U.S.	5	10	15	20	25

Phased-in incrementally over five years, this option will help facilitate the reopening and expansion of U.S. uranium mining, milling, and conversion facilities, and will ensure that U.S. uranium producers can make investments required for future financial viability without causing unintentional harm to other market economy uranium producers. This option avoids undue financial harm to U.S. nuclear power utilities by affording them sufficient time to adjust their fuel procurement strategies.

The zero quota on uranium imports from SOE countries would not apply to uranium imports from SOE countries for use by U.S. milling, conversion,

enrichment, and fuel fabrication services' that produce uranium products for export from the United States. A U.S. milling, conversion, enrichment, or fuel fabricator seeking to import uranium from an SOE country for use to produce uranium products for export would need to file appropriate documentation with the Department to obtain a waiver for the import of such uranium for export.

The Secretary believes that this option to impose a zero quota for imports of uranium from SOE countries, while continuing to allow unrestricted importation of uranium from Canada, Australia, and EURATOM member countries based on their security and economic relationships with the United States, should address the threatened impairment of U.S. national security. This would be accomplished by promoting the economic revival of the U.S. uranium industry, so long as there is not significant transshipment or reprocessing of SOE country uranium through these unrestricted countries. The Department will monitor these unrestricted imports to ensure there is not significant transshipment, reprocessing, or book transfers from SOE countries to unrestricted countries in an attempt to circumvent and undermine the U.S. uranium producers' ability to provide 25 percent of U.S. annual U308 concentrate consumption. Many companies in unrestricted countries supply uranium sourced from SOE countries. Consequently, up to one-third of the materials delivered to U.S. nuclear power utilities, at this time, are not sourced directly from the country of import.

Imports of uranium from Russia under a waiver would also be subjected to the Russian Suspension Agreement. This option assumes that such agreement will continue to be in effect over the relevant time period and would apply to any Russian uranium imports by U.S. nuclear power utilities, thus holding Russian uranium imports to their current level of approximately 20 percent of U.S. enrichment demand. In the event that the Russian Suspension Agreement is not extended and terminates, then the Secretary recommends that a quota on uranium imports under a waiver of Russian Uranium Products (as defined in the Russian Suspension Agreement) of up to 15 percent of U.S. enrichment demand be imposed. If adopted this quota would be administered by the Department in the same manner as the Russian Suspension Agreement is presently administered.

The adjustment of imports proposed under this option would be in addition to any applicable antidumping or countervailing duties collections.

To complement the proposed trade action, the Secretary recommends that the Federal Energy Regulatory Commission (FERC) act promptly to ensure that regulated wholesale power market regulations adequately compensate nuclear and other fuel-secure generation resources. Specifically, FERC should determine whether current market rules, which discriminate against secure nuclear fuel generation resources in favor of intermittent resources, such as natural gas, solar, and wind, result in unjust, unreasonable, and unduly discriminatory rates that distort energy markets, harm consumers, and undermine electric reliability. If so, FERC should consider taking appropriate action to ensure that rates are just and reasonable.

The Department of Commerce, in consultation with other appropriate departments and agencies, will monitor the status of the U.S. uranium industry and the effectiveness of this remedy and will make recommendations to the President regarding whether it should be modified, extended, or terminated.

Option 2—Global Zero Quota

This option would establish a zero quota on imports of uranium from all countries until specific conditions are met to enable U.S. producers to supply 25 percent of U.S. nuclear power utilities' annual consumption of uranium U308 concentrate. A U.S. nuclear power utility or other domestic user would be eligible for a waiver to import uranium from any country after submitting appropriate documentation to the Department. In the case of a U.S. nuclear power utility, the documentation must show that such utility has a contract or contracts to purchase for their consumption on an annual basis not less than the percentage of U.S. produced uranium U308 concentrate shown in the phase-in table below.

PERCENT OF ANNUAL U308 CONCENTRATE CONSUMPTION REQUIRED TO BE SOURCED FROM THE U.S.

Year	2020	2021	2022	2023	2024 and beyond
Percent of Annual U308 Concentrate Consumption Required to be Sourced from the U.S.	5	10	15	20	25

Phased-in incrementally over five years, this option will help facilitate the reopening and expansion of U.S. uranium mining, milling, and conversion facilities, and will ensure that U.S. uranium producers can make investments required for future financial viability. This option avoids undue financial harm to U.S. nuclear power utilities by affording them sufficient time to adjust their fuel procurement strategies.

The zero quota on uranium imports would not apply to uranium imports for use by U.S. milling, conversion, enrichment, and fuel fabrication services' that produce uranium products for export from the United States. A U.S. milling, conversion, enrichment, or fuel fabricator seeking to import uranium for use to produce uranium products for export would need to file appropriate documentation with the Department to obtain a waiver for the import of uranium for export.

The Department will provide adequate time for U.S. industry to receive a waiver prior to a zero quota being implemented globally. Based on information received during the investigation, the Department believes that this option will not cause undue burdens.

The Secretary believes that this option to impose a zero quota for imports of uranium will address the threatened impairment of U.S. national security by promoting the economic revival of the U.S. uranium industry. This option also prevents the possibility of transshipment of SOE overproduction through third countries and avoids undue harm to U.S. enrichment and fuel fabrication export operations. These domestic export operations rely on an ability to access working uranium stock regardless of the specific mining origin of a given uranium-based material.

Tennessee Valley Authority (TVA) purchases of Canadian UO_3 natural uranium diluent in its execution of the National Nuclear Security Administration's current highly-enriched uranium (HEU) down-blending campaign would be excluded from the zero quota on imports of uranium. In addition, any transfer pursuant to a

Mutual Defense Agreement that references special nuclear material would be excluded from the zero quota on imports of uranium.

Imports of uranium from Russia under a waiver would also be governed by the Russian Suspension Agreement. This option assumes that such agreement will continue to be in effect over the relevant time period and would apply to any Russian uranium imports by U.S. nuclear power utilities, thus holding Russian uranium imports to their current level of approximately 20 percent of U.S. enrichment demand. In the event that the Russian Suspension Agreement is not extended and terminates, then the Secretary recommends that a quota on uranium imports under a waiver of Russian Uranium Products (as defined in the Russian Suspension Agreement) of up to 15 percent of U.S. enrichment demand be imposed. If adopted this quota would be administered by the Department in the same manner as the Russian Suspension Agreement is presently administered.

The adjustment of imports proposed under this option would be in addition to any applicable antidumping or countervailing duties collections.

To complement the proposed trade action, the Secretary recommends that the Federal Energy Regulatory Commission (FERC) act promptly to ensure that regulated wholesale power market regulations adequately compensate nuclear and other fuel-secure generation resources. Specifically, FERC should determine whether current market rules, which discriminate against secure nuclear fuel generation resources in favor of intermittent resources, such as natural gas, solar, and wind, result in unjust, unreasonable, and unduly discriminatory rates that distort energy markets, harm consumers, and undermine electric reliability. If so, FERC should consider taking appropriate action to ensure that rates are just and reasonable.

The Department of Commerce, in consultation with other appropriate departments and agencies, will monitor the status of the U.S. uranium industry and the effectiveness of this remedy to determine if it should be modified, extended, or terminated.

Option 3—Alternative Action

Should the President determine that the threatened impairment of national security does not warrant immediate adjustment of uranium imports at this time but that alternative action should be taken to improve the condition of the U.S. uranium industry to enable the U.S. industry to supply 25 percent of U.S nuclear power utilities annual consumption of uranium U308 concentrate, the President could direct the Department of Defense (DOD) and the Department of Energy (DOE) to report to the President within 90 days on options for increasing the economic viability of the domestic uranium mining industry. The report should include, but not be limited to, recommendations for: (1) The elimination of regulatory constraints on domestic producers; (2) incentives for increasing investment; and (3) ways to work with likeminded allies to address unfair trade practices by SOE countries, including through trade remedy actions and the negotiation of new rules and best practices. The President could also direct the United States Trade Representative to enter into negotiations with the SOE countries to address the causes of excess uranium imports that threaten the national security.

To complement the proposed alternative action, the Secretary recommends that the Federal Energy Regulatory Commission (FERC) act promptly to ensure that regulated wholesale power market regulations adequately compensate nuclear and other fuel-secure generation resources. Specifically, FERC should determine whether current market rules, which discriminate against secure nuclear fuel generation resources in favor of intermittent resources, such as natural gas, solar, and wind, result in unjust, unreasonable, and unduly discriminatory rates that distort energy markets, harm consumers, and undermine electric reliability. If so, FERC should consider taking appropriate action to ensure that rates are just and reasonable.

The Department of Commerce, in consultation with other appropriate departments and agencies, will monitor the status of the U.S. uranium industry and the effectiveness of this remedy and recommend to the President if any additional measures are needed. Alternatively, the Secretary may initiate another investigation under Section 232.

B. Economic Impact of 25 Percent U.S.-Origin Requirement

The Department analyzed the economic impact of a 25 percent U.S.-origin uranium concentrate requirement on the U.S. uranium mining industry as well as U.S. nuclear power utilities. The Department's analysis and modeling indicates that U.S. uranium mining and milling will substantially benefit from the 25 percent U.S.-origin uranium concentrate requirement and will return to an economically competitive and financially viable industry. U.S. nuclear power utilities will experience only marginal increases in fuel costs and slight decreases in revenue due to usage of U.S.-origin uranium concentrate for 25 percent of their fuel supply.

The Department's analysis indicates if Option 1 or 2 is implemented, U.S. uranium producers between 2020 and 2024 will see a substantial increase in their production compared to the projected 2019 level of 331,000 pounds U3O8 equivalent (*see* Figure 72).

Figure 72. Projected U.S. Uranium Concentrate Production and Per-Pound Price, 2020-2024

Price Per Pound Given Projected U.S. Demand		
Year, U.S. Content Required	Projected U.S. Concentrate Demand (Lbs. U308)	Projected Price Per Lb.
2020, 5%	1,208,975	$36.21
2021, 10%	2,417,951	$41.23
2022, 15%	3,626,926	$46.26
2023, 20%	4,835,901	$51.29
2024, 25%	6,044,877	$56.31

Source: U.S. Department of Commerce, Bureau of Industry and Security, Front-End Survey, Q4B

13 respondents

Over the five-year implementation, U.S. uranium concentrate producers, including mines and mills, will see prices rise to a level that will support sustained production of approximately 6 million pounds U3O8 equivalent per year, or 25 percent of U.S. concentrate requirements based on 2018 data.

[TEXT REDACTED] By acquiring more U.S.-origin uranium concentrate, U.S. utilities will need to have at least some of that material converted domestically. [TEXT REDACTED]

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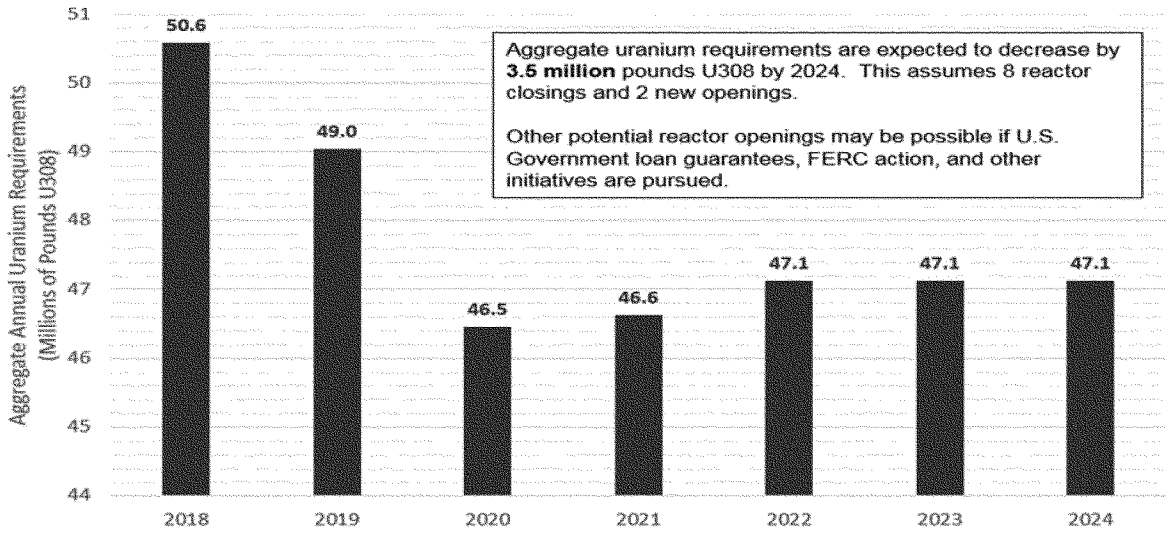
[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED]
[TEXT REDACTED] [TEXT REDACTED]

[TEXT REDACTED] Preserving ConverDyn's conversion capacity is imperative to preserving the U.S.'s entire nuclear fuel cycle capabilities, particularly as DOE looks to build a new enrichment facility in the coming decades.

U.S. utilities will experience only marginal effects from the 25 percent U.S.-origin requirement. Due to reactor retirements, overall uranium requirements are expected to decrease by approximately 6.9 percent over the next five years (*see* Figure 74).

Figure 74. U.S. Utility Uranium Requirements, 2018; Projected 2019-2024



Source: U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power Generator Survey, Q3B

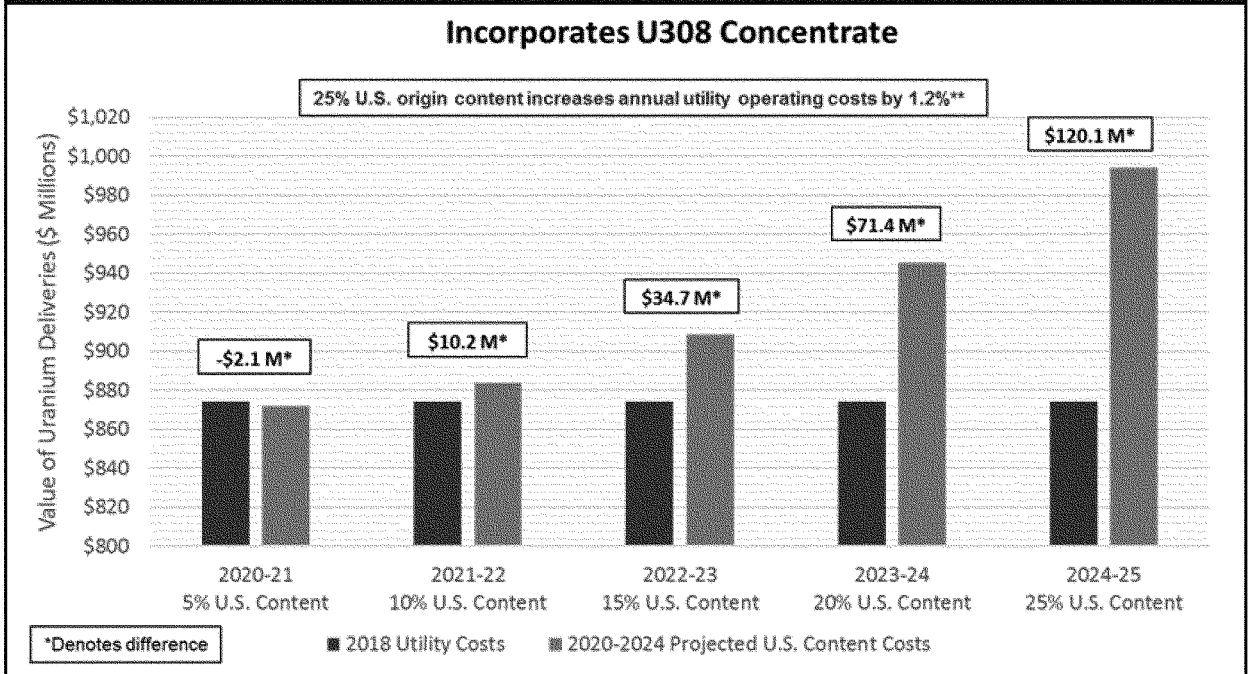
98 reactors

BILLING CODE 3510–33–C

Based on this projected level of consumption, the Department's modelling indicates that a 25 percent U.S.-origin requirement will increase aggregate utility fuel costs by $120.1 million, or 13.72 percent, between 2020

and 2024. This is based on aggregated utility fuel costs of nearly $900 million in 2018 (*see* Figure 75).

Figure 75. U.S. Utility Aggregate Change in Projected Operating Costs: Phased-In 25 Percent U.S. Origin Requirement, 2020-2024



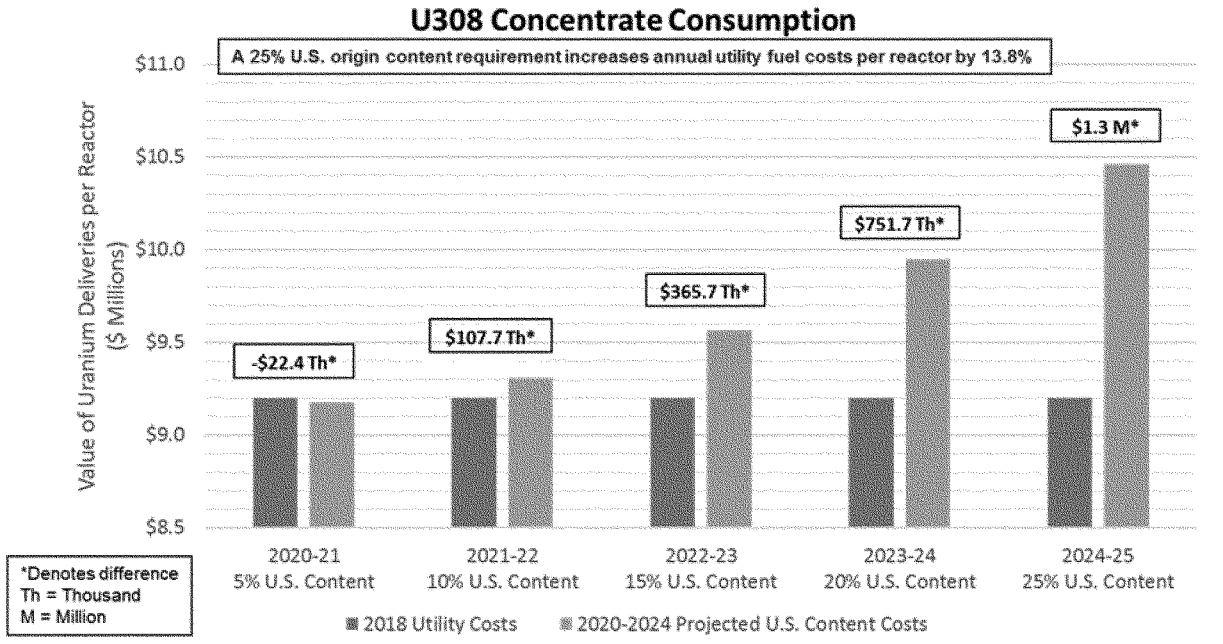
**This includes financial data for both utilities reporting at the company-wide level as well as nuclear-specific operating units. [TEXT REDACTED] were not included due to improperly submitted data.

Source: U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power Generator Survey, Q9BQ

20 respondents

On a per-reactor basis, the 25 percent U.S.-origin requirement will increase fuel costs by approximately $1.3 million, or 13.76 percent, between 2020 and 2024. This calculation is based on overall fuel reactor costs of nearly $9.2 million per reactor in 2018 (*see* Figure 76).

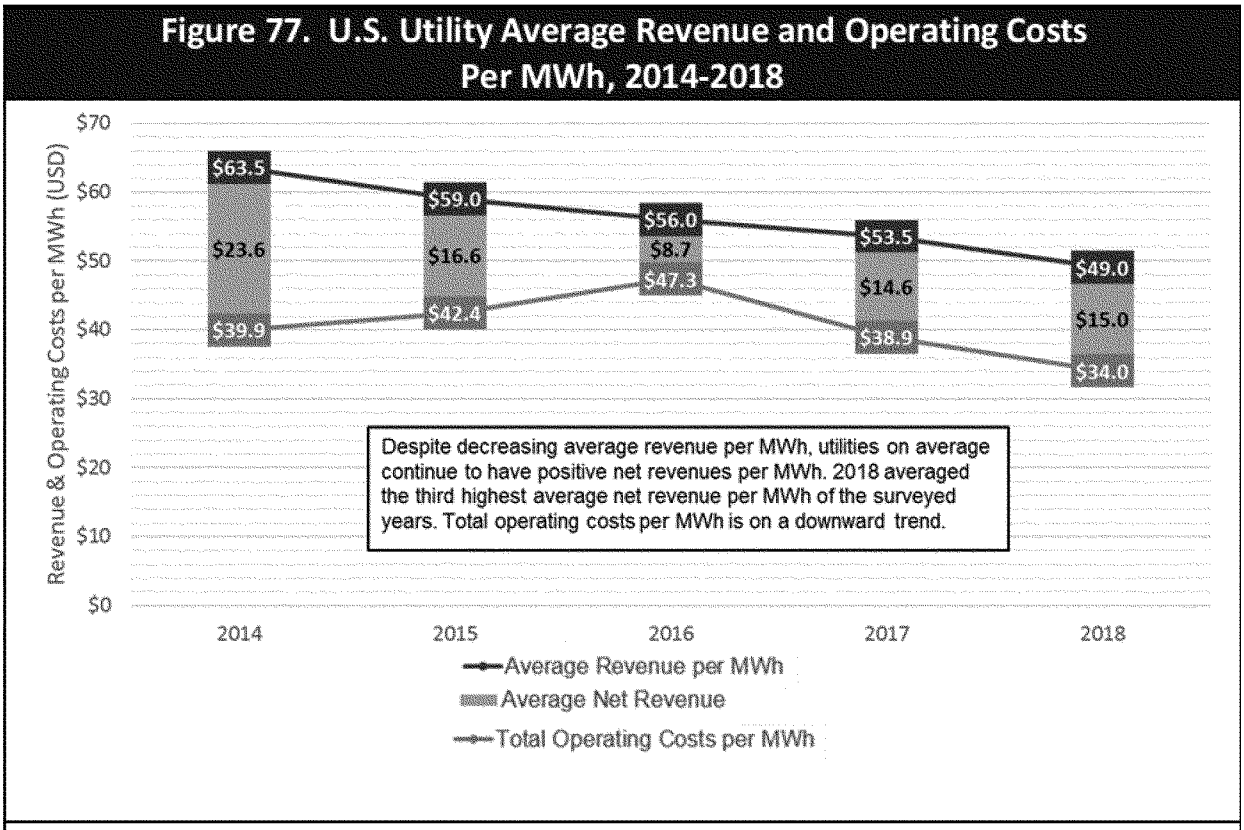
Figure 76. U.S. Utility Per-Reactor Change in Projected Fuel Costs: Phased-In 25 Percent U.S. Origin Requirement, 2020-2024



Source: U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power GeneratorSurvey, Q9B-Q
*[TEXT REDACTED] were not included due to improperly submitted data.

*95 reactors**

On a per-megawatt hour (MWh) basis, the Department's data shows that U.S. nuclear electric utilities have experienced declining average net revenues since 2014. Between 2014 and 2016, average net revenues per MWh dropped from $23.60 to $15.00, a 36.4 percent decline. However, average net revenues have recovered since 2016. U.S. nuclear electric utilities reported an average per-MWh net revenue of $15.00 in 2018 (*see* Figure 77).



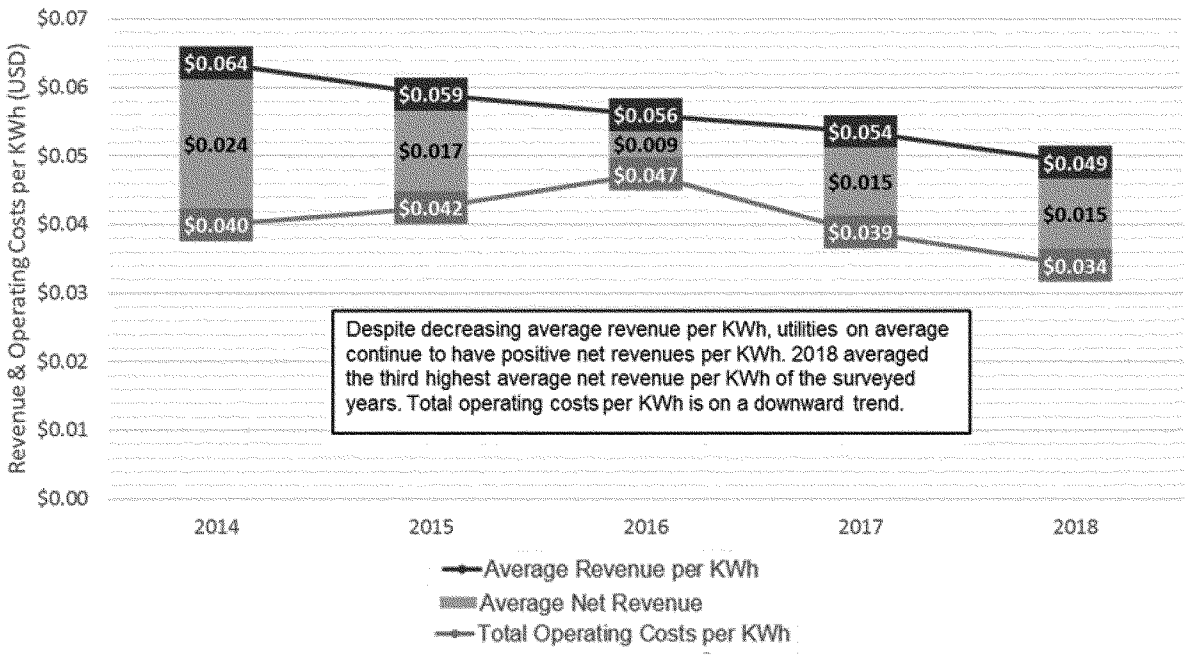
**Excludes [TEXT REDACTED]

Source: U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power Generator Survey, Q6C

20 respondents

A similar trend can be observed on a per kilowatt-hour (KWh) basis. U.S. utility per-KWh revenues fell from $0.024 in 2014 to just $0.009 in 2016 before increasing to $0.015 in 2018 (*see* Figure 78):

Figure 78. U.S. Utility Average Revenue and Operating Costs Per KWh, 2014-2018

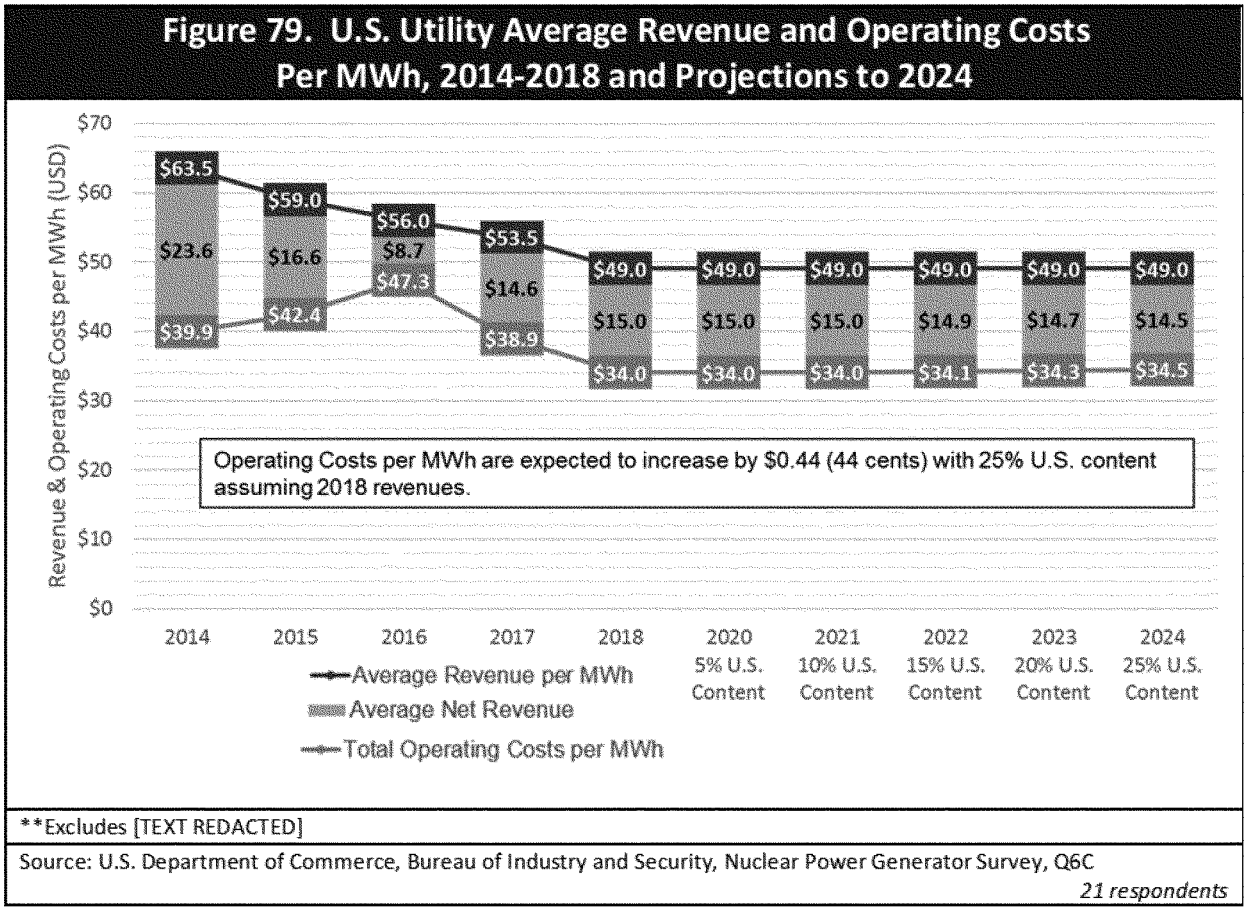


**[TEXT REDACTED]

Source: U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power Generator Survey, Q6C

20 respondents

The Department's analysis also projected the U.S.-origin requirement through 2024. The Department's analysis concludes that U.S. utility operating costs per MWh will increase to $34.45 in 2024, a small 1.29 percent increase over the projected 2020 cost of $34.01. U.S. utility average net revenues per MWh will drop slightly to $14.50, a marginal 3.4 percent decline compared to projected 2020 net revenues of $15.01 (*see* Figure 79).



**Excludes [TEXT REDACTED]

Source: U.S. Department of Commerce, Bureau of Industry and Security, Nuclear Power Generator Survey, Q6C

21 respondents

C. Public Policy Proposals

The Secretary finds that the effect of imported uranium on the national security can only be addressed through targeted Section 232 remedies. The Secretary has noted that the U.S. uranium industry and nuclear power generators face other non-trade challenges that hinder their ability to remain financially solvent and economically competitive.

These challenges, as discussed in Chapters VI and VII, include the premature shutdown of U.S. reactors, competition from natural gas-fired generators, and subsidized renewable energy sources. In addition, the nuclear power industry is hindered by electricity market rules that do not consider nuclear energy's unique operational attributes. To address these issues, the Secretary advances the following public policy proposals for discussion which complement the Section 232 remedies identified in this investigation.[155]

(1) Expansion of the American Assured Fuel Supply (AFS)

The Department of Energy maintains a reserve of enriched uranium for nuclear power generators known as the American Assured Fuel Supply (AFS), which is an emergency source of fuel for both U.S. and foreign nuclear power plants.[156] The AFS currently includes 230 metric tons of LEU, only enough material to reload six average nuclear reactors once (the U.S. has 98 reactors).[157] DOE should increase the AFS's inventory to 500 metric tons of LEU, enough to fuel 13 reactors in the U.S. and allied countries. This could supplement the [TEXT REDACTED] average inventory U.S. nuclear power utilities already maintain (*see* Figure 66). The LEU procured for the AFS should come from newly mined, converted, and enriched U.S.-origin uranium.

(2) Adoption of a Domestic Uranium Purchase Tax Credit

Congress should institute a tax credit for domestic uranium purchases for a five-year period. Under this proposal, U.S. nuclear power generators would receive a fixed dollar amount-per pound tax credit for purchasing uranium mined in the United States. The credit would be claimable in the tax year in which the nuclear power generator takes delivery of the material.

(3) Continue the Moratorium on DOE Stockpile Sales

Under the Atomic Energy Act of 1954, the DOE possesses authority to sell or transfer its stockpiles to other parties.[158] DOE has used this authority to pay for cleanup efforts at the Portsmouth Gaseous Diffusion Facility. While DOE's

[155] Section V of the January 1989 Section 232 investigation into crude oil and refined petroleum imports contained several non-trade policy recommendations to be executed by Congress or other Federal departments. These recommendations included implementation of an oil and gas leasing plan, opening the Arctic National Wildlife Refuge to oil exploration, oil and gas licensing reform, and technical tax changes. U.S. Department of Commerce, Bureau of Export Administration; ''The Effect of Crude Oil and Refined Petroleum Product Imports On The National Security''; January 1989.

[156] In 2005, the Department of Energy (DOE) announced that it would set aside 17.4 metric tons of highly-enriched uranium (HEU) for conversion to low-enriched uranium (LEU) that could be released to nuclear power generators in times of national emergency.

[157] *Notice of Availability: American Assured Fuel Supply. The Federal Register/FIND.* Vol. 76. Washington: Federal Information & News Dispatch, Inc., 2011. *http://search.proquest.com/docview/884208970/.*

[158] U.S. Government Accountability Office. *Highlights of GAO–17–472T, a testimony before the Committee on Environment and Public Works, U.S. Senate,* 5. (Washington, DC: Mar. 8, 2017). *https://www.gao.gov/assets/690/683764.pdf.*

determination process evaluates whether DOE transfers are having a material effect on the industry, respondents to the Department's 2019 uranium survey have reported that DOE's uranium transfer program has negatively impacted uranium producers' business. Congress should block further transfers of DOE stockpile material.

(4) State Adoption of Zero Emissions Credits

Implement zero emissions credits (ZEC) to compensate nuclear power generators for the value of the zero-emissions electricity that they produce. ZECs will help nuclear generators fairly compete against renewable sources such as solar and wind, which are subsidized through the federal production tax credit (PTC) and similar state subsidies. ZECs, if adopted by more states, may halt some current U.S. reactor retirements and solidify utility demand for U.S.-produced uranium.

(5) Mandate That Federal Departments and Agencies Use Nuclear Power

The Federal government can support U.S. nuclear power generation by requiring Federal departments and agencies to purchase an average of 20 percent of their power from nuclear power plants for a period of five years at a fixed price. This would provide predictable demand for nuclear power generators.

(6) Expand the Responsibilities of the Nuclear Materials Management and Safeguard Systems (NMMSS)

The 123 Agreements do not require tracking and reporting of ''mining origin'' data for nuclear material subject to peaceful use provisions. Furthermore, the domestic U.S. operators are not required to report origin data to NMMSS for imports, exports, and other nuclear material inventory changes.

NMMSS, as the national U.S. system of nuclear material accounting, can add the capability to track mining origin data. However, this outcome required changes impacting NRC regulations, 123 Agreements, and industry practices.

The Secretary recommends that the NRC and NNSA work with the Departments of Commerce, Defense, Energy, Homeland Security, and Justice to examine potential options and mechanisms to enable the reporting of origin data to NMMSS, and to coordinate with NMMSS to identify actions necessary for changes to the system.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

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Part III

Securities and Exchange Commission

Order Granting Conditional Substituted Compliance in Connection With Certain Requirements Applicable to Non-U.S. Security-Based Swap Dealers and Major Security-Based Swap Participants Subject to Regulation in the French Republic; Notice

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–92484; File No. S7–22–20]

Order Granting Conditional Substituted Compliance in Connection With Certain Requirements Applicable to Non-U.S. Security-Based Swap Dealers and Major Security-Based Swap Participants Subject to Regulation in the French Republic

July 23, 2021.

I. Overview

The French Autorité des Marchés Financiers (''AMF'') and the Autorité de Contrôle Prudentiel et de Résolution (''ACPR''), the French financial authorities, have submitted a ''substituted compliance'' application requesting that the Securities and Exchange Commission (''Commission'') determine, pursuant to the Securities Exchange Act of 1934 (''Exchange Act'') rule 3a71–6, that security-based swap dealers and major security-based swap participants (''SBS Entities'') subject to regulation in the French Republic (''France'') conditionally may satisfy requirements under the Exchange Act by complying with comparable French and European Union (''EU'') requirements.[1] The AMF and the ACPR (''French Authorities'') sought substituted compliance in connection with certain Exchange Act requirements related to risk control, capital and margin, internal supervision and compliance, counterparty protection, and record keeping, reporting, notification, and securities counts.[2] The application incorporated comparability analyses between the relevant requirements in Exchange Act section 15F and the rules and regulations thereunder and applicable French and EU law, as well as information regarding French supervisory and enforcement frameworks.

On December 22, 2020, the Commission issued a notice of the French Authorities' Application, accompanied by a proposed order to grant substituted compliance with conditions in connection with the French Authorities' Application (the ''proposed Order'').[3] The proposed Order incorporated a number of conditions to tailor the scope of substituted compliance consistent with the prerequisite that relevant French and EU requirements produce regulatory outcomes that are comparable to relevant requirements under the Exchange Act. The Commission reopened the comment period for the proposed Order on April 5, 2021.[4]

As discussed below, the Commission is adopting a final Order that has been modified from the proposal in certain respects to address commenter concerns and to make clarifying changes.

II. Substituted Compliance Framework, Prerequisites and Commenter Issues of General Applicability

A. Substituted Compliance Framework and Purpose

As the Commission has discussed previously,[5] Exchange Act rule 3a71–6 provides a framework whereby non-U.S. SBS Entities may satisfy certain requirements under Exchange Act section 15F by complying with comparable regulatory requirements of a foreign jurisdiction.[6] Because substituted compliance does not constitute exemptive relief, but instead provides an alternative method by which non-U.S. SBS Entities may comply with applicable Exchange Act requirements, the non-U.S. SBS Entities would remain subject to the relevant requirements under section 15F. The Commission accordingly will retain the authority to inspect, examine and supervise those SBS Entities' compliance and take enforcement action as appropriate. Under the substituted compliance framework, failure to comply with the applicable foreign requirements and other conditions to a substituted compliance order would lead to a violation of the applicable requirements under the Exchange Act and potential enforcement action by the Commission (as opposed to automatic revocation of the substituted compliance order).

Under rule 3a71–6, substituted compliance potentially is available in connection with certain section 15F requirements,[7] but is not available in connection with antifraud prohibitions and certain other requirements under the Federal securities laws.[8] SBS Entities in France accordingly must comply directly with those requirements notwithstanding the availability of substituted compliance for other requirements.

The substituted compliance framework reflects the cross-border nature of the security-based swap market, and is intended to promote efficiency and competition by helping to address potential duplication and inconsistency between relevant U.S. and foreign requirements.[9] In practice, substituted compliance may be expected to help SBS Entities leverage their existing systems and practices to comply with relevant Exchange Act requirements in conjunction with their compliance with relevant foreign requirements. Market participants will begin to count security-based swap transactions toward the thresholds for registration with the Commission as an SBS Entity on August 6, 2021, and will be required to begin registering with the Commission on November 1, 2021.[10]

[1] *See* Letter from Robert Ophèle, Chairman, AMF, and Denis Beau, Chairman, ACPR, to Vanessa Countryman, Secretary, Commission, dated Dec. 9, 2020 (''French Authorities' Application''). The application is available on the Commission's website at: *https://www.sec.gov/files/full-french-application.pdf.*

[2] ''Risk control'' includes requirements related to internal risk management, trade acknowledgment and verification, portfolio reconciliation and dispute resolution, portfolio compression and trading relationship documentation; ''capital and margin'' includes requirements related to capital applicable to non-prudentially regulated security-based swap dealers and to margin applicable to non-prudentially regulated SBS Entities; ''internal supervision and compliance'' includes requirements related to diligent supervision, conflicts of interest, information gathering under Exchange Act section 15F(j), 15 U.S.C. 78*o*–10(j), and chief compliance officers; ''counterparty protection'' includes requirements related to disclosure of material risks and characteristics and material incentives or conflicts of interest, ''know your counterparty,'' suitability of recommendations, fair and balanced communications, disclosure of daily marks and disclosure of clearing rights; and ''record keeping, reporting, notification, and securities counts'' includes requirements related to making and keeping current certain prescribed records, preservation of records, reporting, notification and securities counts.

[3] *See* Exchange Act Release No. 90766 (Dec. 22, 2020), 85 FR 85720, 85721 (Dec. 29, 2020) (''French Substituted Compliance Notice and Proposed Order'').

[4] *See* Exchange Act Release No. 91477 (Apr. 5, 2021), 86 FR 18341 (Apr. 8, 2021) (''Reopening Release''). The reopened comment period ended on May 3, 2021.

[5] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85721; Exchange Act Release No. 90765 (Dec. 22, 2020), 85 FR 85686, 85687 (Dec. 29, 2020) (''German Substituted Compliance Order'').

[6] *See* Exchange Act Release No. 77617 (Apr. 14, 2016), 81 FR 29960, 30079 (May 13, 2016) (''Business Conduct Adopting Release'').

[7] 17 CFR 240.3a71–6(d).

[8] French Substituted Compliance Notice and Proposed Order, 85 FR at 85721 n.2 (addressing unavailability of substituted compliance in connection with antifraud provisions, as well as provisions related to transactions with counterparties that are not eligible contract participants (''ECPs''), segregation of customer assets, required clearing upon counterparty election, regulatory reporting and public dissemination, and registration of offerings).

[9] *See generally* Business Conduct Adopting Release, 81 FR at 30073 (noting that the cross-border nature of the security-based swap market poses special regulatory challenges, in that relevant U.S. requirements ''have the potential to lead to requirements that are duplicative of or in conflict with applicable foreign business conduct requirements, even when the two sets of requirements implement similar goals and lead to similar results'').

[10] *See* ''Key Dates for Registration of Security-Based Swap Dealers and Major Security-Based Swap Participants,'' available at *https://www.sec.gov/page/key-dates-registration-security-*

Substituted compliance should assist relevant non-U.S. security-based swap market participants in preparing for registration.

B. Scope of Substituted Compliance

For entity-level Exchange Act requirements,[11] a Covered Entity must choose either to apply substituted compliance pursuant to the Order with respect to all security-based swap business subject to the relevant French and EU requirements or to comply directly with the Exchange Act with respect to all such business; a Covered Entity may not choose to apply substituted compliance for some of the business subject to the relevant French or EU requirements and comply directly with the Exchange Act for another part of the business that is subject to the relevant French and EU requirements. Additionally, for entity-level Exchange Act requirements, if the Covered Entity also has security-based swap business that is not subject to the relevant French requirements, the Covered Entity must either comply directly with the Exchange Act for that business or comply with the terms of another applicable substituted compliance order.[12] For transaction-level Exchange Act requirements,[13] a Covered Entity may decide to apply substituted compliance for some of its security-based swap business and to comply directly with the Exchange Act (or comply with another applicable substituted compliance order) for other parts of its security-based swap business.

C. Specific Prerequisites

1. Comparability of Regulatory Outcomes

Rule 3a71–6, adopted by the Commission in 2016, describes the requirements for the Commission to make a substituted compliance determination. Under the rule, the Commission must determine that the analogous foreign requirements are comparable to otherwise applicable requirements under the Exchange Act (*i.e.,* the relevant requirements in the Exchange Act and the rules and regulations thereunder), after accounting for factors such as ''the scope and objectives of the relevant foreign regulatory requirements'' and ''the effectiveness of the supervisory compliance program administered, and the enforcement authority exercised'' by the foreign authority.[14] The comparability assessments are to be based on a ''holistic approach'' that ''will focus on the comparability of regulatory outcomes rather than predicating substituted compliance on requirement-by-requirement similarity.'' [15]

2. Memoranda of Understanding

Exchange Act rule 3a71–6(a)(2)(ii) further predicates the availability of substituted compliance on the Commission and the foreign financial regulatory authority or authorities entering into a supervisory and enforcement memorandum of understanding and/or other arrangement with the relevant foreign financial regulatory authorities ''addressing supervisory and enforcement cooperation and other matters arising under the substituted compliance determination.'' [16] Accordingly, the Commission and the AMF and the ACPR recently entered into a relevant memorandum of understanding.[17] Moreover, the Commission and the European Central Bank (''ECB'') are in the process of developing a memorandum of understanding or other arrangement to address cooperation matters related to substituted compliance.[18] Those memoranda of understanding or other arrangements must be in place before Covered Entities may use substituted compliance to satisfy obligations under the Exchange Act.[19]

3. ''Adequate assurances''

A foreign financial regulatory authority may submit a substituted compliance application only if the authority provides ''adequate assurances'' that no law or policy would impede the ability of any entity that is directly supervised by the authority and that may register with the Commission ''to provide prompt access to the Commission to such entity's books and records or to submit to onsite inspection or examination by the Commission.'' [20]

based-swap-dealers-and-major-security-based-swap-participants.

[11] The entity-level requirements relate to capital and margin, books and records (other than those linked to the counterparty protection rules), internal risk management systems, trade acknowledgement and verification, portfolio reconciliation, compression, trading relationship documentation, and internal supervision and chief compliance officer requirements. *See* Exchange Act Release No. 86175 (June 21, 2019) 84 FR 43872, 43879 (Aug 22, 2019) (''Capital and Margin Adopting Release''); Exchange Act Release No. 87005 (June 19, 2019) 84 FR 68550, 68596 (Dec. 16, 2019) (''Books and Records Adopting Release''); Exchange Act Release No. 78011 (June 8, 2016) 81 FR 39808, 39827 (June 17, 2016) (''TAV Adopting Release''); Exchange Act Adopting Release No. 87782 (Dec. 18, 2019) 85 FR 6359, 6378 (Feb. 4, 2020) (''Risk Mitigation Adopting Release''); Business Conduct Adopting Release, 81 FR at 30064. Transaction-level requirements encompass business conduct requirements for the protection of counterparties, and additional provisions for the protection of special entities. *See also* Business Conduct Adopting Release, 81 FR at 30065.

[12] In the context of the EMIR counterparties condition in paragraph (a)(5), a Covered Entity must choose: (1) To apply substituted compliance pursuant to the Order—including compliance with paragraph (a)(5) as applicable—for a particular set of entity-level requirements with respect to all of its business that would be subject to the relevant EMIR-based requirement if the counterparty were the relevant type of counterparty; or (2) to comply directly with the Exchange Act with respect to such business.

[13] Transaction-level requirements are the counterparty protection requirements and the books and records requirements related to those counterparty protection requirements.

[14] Exchange Act rule 3a71–6(a)(2)(i).

[15] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85722; *see also* Business Conduct Adopting Release, 81 FR at 30078–79 (further recognizing that ''different regulatory systems may be able to achieve some or all of those regulatory outcomes by using more or fewer specific requirements than the Commission, and that in assessing comparability the Commission may need to take into account the manner in which other regulatory systems are informed by business and market practices in those jurisdictions''). The Commission's assessment of a foreign authority's supervisory and enforcement effectiveness—as part of the broader comparability analysis—would be expected to consider not only overall oversight activities, but also oversight specifically directed at conduct and activity relevant to the substituted compliance determination. ''For example, it would be difficult for the Commission to make a comparability determination in support of substituted compliance if oversight is directed solely at the local activities of foreign security-based swap dealers, as opposed to the cross-border activities of such dealers.'' Business Conduct Adopting Release, 81 FR at 30079 (footnote omitted). In the French Substituted Compliance Notice and Proposed Order, the Commission preliminarily concluded that this comparability prerequisite was met in connection with a number of requirements under the Exchange Act, in some cases with the addition of conditions to help ensure the comparability of regulatory outcomes.

[16] Exchange Act rule 3a71–6(a)(2)(ii).

[17] The Commission, the AMF and the ACPR have entered into a memorandum of understanding to address substituted compliance cooperation, a copy of which is on the Commission's website at *www.sec.gov* under the ''Substituted Compliance'' tab, which is located on the ''Security-Based Swap Markets'' page in the Division of Trading and Markets section of the site (''AMF and ACPR MOU''). The AMF, ACPR and the ECB share responsibility for supervising compliance with certain provisions of EU and French law.

[18] The memorandum of understanding will set forth the conditions under which supervisory and enforcement information for certain subject matters, including but not limited to margin and capital, that is owned by the ECB, can be requested, shared, used and protected from unauthorized disclosure by the SEC and ECB. The memorandum of understanding will also serve as a framework for consultation, cooperation and the exchange of information between the SEC and the ECB in the supervision, enforcement and oversight of the covered firms.

[19] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85721 n.4. The Commission expects to publish any such memoranda of understanding or arrangements on its website at *www.sec.gov* under the ''Substituted Compliance'' tab, which is located on the ''Security-Based Swap Markets'' page in the Division of Trading and Markets section of the site.

[20] *See* Exchange Act rule 3a71–6(c)(3).

In the French Substituted Compliance Notice and Proposed Order, the Commission stated that the French Authorities had satisfied this prerequisite in the Commission's preliminary view, taking into account information and representations that the French Authorities provided regarding certain French and EU requirements that are relevant to the Commission's ability to inspect, and access the books and records of, firms using substituted compliance pursuant to the Order.[21] The Commission received no comments on this preliminary view and has not changed its view.

D. Commenter Views of General Applicability

As the Commission previously discussed, commenters raised a variety of concerns and other views regarding specific aspects of the proposed Order (apart from certain global concerns addressed below in part II.D.1 through 4.[22] Those included: Concerns that the interplay between certain proposed MiFID-related conditions to substituted compliance for risk control requirements and a proposed EU cross-border condition would undermine the availability of substituted compliance; [23] views regarding the possibility of substituted compliance related to capital; [24] and views regarding substituted compliance in connection with books and records requirements.[25]

The Commission reopened the comment period in April 2021.[26] The Commission also requested comment on a number of specific issues, including: The potential removal of MiFID provisions from the trade acknowledgment and verification and trading relationship documentation conditions in conjunction with additional general conditions to address the resulting increased reliance upon EMIR; [27] the inclusion of additional capital standards; [28] the availability of greater flexibility in distinguishing between recordkeeping and reporting requirements; [29] limiting the definition of ''covered entity''; [30] and supplementing the internal supervision and compliance conditions.[31] In response, commenters expressed a range of views and identified a number of specific issues with the proposed conditions and prerequisites for each subject matter of the proposed Order for which substituted compliance is available.[32]

1. Effects of Non-Compliance

One commenter addressed a Commission statement that non-compliance with applicable French and EU requirements would lead to a violation of relevant requirements under the Exchange Act. The commenter particularly requested that the Commission represent that SBS Entities ''would not violate the Commission's requirements where the relevant foreign regulatory authority has found no violation of the comparable French or EU requirement and the SBS Entity's conduct would have complied with the Commission's requirements (even if the SBS Entity relied on French and EU rules that imposed stricter or additional requirements).'' [33] The commenter also expressed a concern that the Commission might find a violation of the foreign laws even where the Commission's own requirements would be fulfilled.[34] The commenter further requested that the Commission state that it ''will not independently examine for or otherwise assess whether an SBS Entity is complying with EU or French requirements.'' [35]

Although the Commission expects to take the views of foreign regulatory authorities into account when it considers whether registered entities have complied with the conditions to substituted compliance, the Commission cannot make the requested representations. It is for the Commission—not foreign regulators—to determine whether a non-U.S. SBS Entity has complied with the conditions to substituted compliance and with the Federal securities laws. Moreover, as noted, even with substituted compliance the Commission retains its full authority to inspect, examine and supervise registered entities' compliance with the Federal securities laws, and to take enforcement action as appropriate.[36]

2. Prerequisites to Substituted Compliance

One commenter stated that the Commission should make a positive substituted compliance determination only when the Commission determines that granting substituted compliance promotes the protection of the U.S. financial system.[37] The commenter also stated that grants of substituted compliance must be predicated on a ''well-supported, evidence-based determination'' that the relevant foreign requirements will produce ''substantially similar'' regulatory outcomes.[38] Congress gave the Commission authority in Title VII to implement a security-based swap framework to address the potential effects of security-based swap activity on U.S. market participants, the financial stability of the United States, the transparency of the U.S. financial system and the protection of counterparties.[39] When adopting rules regarding the application of Title VII's

[21] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85721 n.5.

[22] *See generally* Reopening Release, 86 FR 18341. *See also* Letter from Kyle Brandon, Managing Director, Head of Derivative Policy, SIFMA (Jan. 25, 2021) (''SIFMA Letter I''); Letter from Wim Mijs, Chief Executive Officer, European Banking Federation (Jan. 25, 2021) (''EBF Letter I'') (generally supporting the SIFMA Letter I); and Letter from Etienne Barel, Deputy Chief Executive Officer, French Banking Federation (Jan. 25, 2021) (''FBF Letter I''). Comments may be found on the Commission's website at: *https://www.sec.gov/comments/s7-22-20/s72220.htm.*

[23] Reopening Release, 86 FR at 18343 (expressing the view that the interplay of those MiFID conditions and the proposed EU cross-border condition ''in practice would undermine the availability of substituted compliance for Covered Entities that have branches in EU Member States for which the Commission has not entered into an applicable substituted compliance memorandum of understanding'').

[24] *Id.* at 18343–47.

[25] *Id.* at 18347–48.

[26] *See* Reopening Release, 86 FR 18341. The reopened comment period ended on May 3, 2021.

[27] *Id.* at 18341–43.

[28] *Id.* at 18343–47.

[29] *Id.* at 18347–48.

[30] *Id.* at 18348.

[31] *Id.*

[32] *See* Letter from Kyle Brandon, Managing Director, Head of Derivative Policy, SIFMA (May 3, 2021) (''SIFMA Letter II''); Letter from Wim Mijs, Chief Executive Officer, European Banking Federation (May 3, 2021) (''EBF Letter II''); Letter from Etienne Barel, Deputy Chief Executive Officer, French Banking Federation (May 3, 2021) (''FBF Letter II''); Letter from Americans for Financial Reform Education Fund (May 3, 2021) (''AFREF Letter''); Letter from Dennis M. Kelleher, President and CEO, Stephen Hall, Legal Director and Securities Specialist, and Jason Grimes, Senior Counsel, Better Markets, Inc. (May 3, 2021) (''Better Markets Letter'') at 3–4. Comments may be found on the Commission's website at: *https://www.sec.gov/comments/s7-22-20/s72220.htm.*

[33] SIFMA Letter I at 9; *see also* FBF Letter I at 2.

[34] *See* SIFMA Letter I at 9 n.22.

[35] SIFMA Letter I at 9.

[36] *See* Business Conduct Adopting Release, 81 FR at 30079.

[37] *See* Better Markets Letter at 3–4.

[38] *See id.* at 4.

[39] *See* Exchange Act Release No. 72472 (June 25, 2014), 79 FR 47278, 47286 (Aug. 12, 2014) (''Cross-Border Entity Definitions Adopting Release'') (citing Pub. L. 111–203, Preamble (stating that the Dodd-Frank Act was enacted ''[t]o promote the financial stability of the United States by improving accountability and transparency in the financial system, to end 'too big to fail', to protect the American taxpayer by ending bailouts, to protect consumers from abusive financial services practices, and for other purposes''); Public Law 111–203, sections 701–774 (providing for, among other things, a comprehensive new regulatory framework for security-based swaps, including by: (i) Providing for the registration and comprehensive regulation of security-based swap dealers and major security-based swap participants; (ii) imposing clearing and trade execution requirements on security-based swaps, subject to certain exceptions; and (iii) creating real-time reporting and public dissemination regimes for security-based swaps)).

definitions of ''security-based swap dealer'' and ''major security-based swap participant'' in the cross-border context, the Commission was guided by the purposes of Title VII and the applicable requirements of the Exchange Act, which include consideration of not only risk to the U.S. financial system but also other factors such as counterparty protection, transparency, prevention of evasion, economic impacts and consultation and coordination with other U.S. financial regulatory authorities and foreign financial regulatory authorities.[40] In its registration rules for these SBS Entities, the Commission determined that a foreign market participant whose U.S.-nexus security-based swap activity qualifies it as an SBS Entity would be required to register as such, without substituted compliance available for registration requirements.[41] The Commission concluded that obliging these foreign persons to register serves an important regulatory function that would be significantly impaired by permitting substituted compliance for registration requirements.[42] This registration requirement thus puts into practice the Commission's consideration of the purposes of Title VII and the applicable requirements of the Exchange Act in its adoption of the definitions of ''security-based swap dealer'' and ''major security-based swap participant'' in the cross-border context, and ensures that such firms will be subject to the jurisdiction of the Commission. Moreover, the rules applicable to these registered foreign SBS Entities reflect the Commission's best judgment for how to achieve the purposes of Title VII and satisfy the requirements of the Exchange Act, including the Commission's consideration of risk to the U.S. financial system.[43]

The Commission's rules for registered foreign SBS Entities thus reflect the Commission's consistent consideration of all of the purposes of Title VII and relevant parts of the Exchange Act, first in the context of its adoption of the definitions of ''security-based swap dealer'' and ''major security-based swap participant,'' then in its decision to require foreign SBS Entities to register and finally in its adoption of cross-border rules for SBS Entities pursuant to Title VII. When making a substituted compliance determination, the Commission's task, as outlined in rule 3a71–6, is to evaluate whether the relevant foreign requirements are comparable to these Title VII-based requirements and relevant provisions of the Exchange Act. The comparability assessments are to be based on a ''holistic, outcomes-oriented framework,''[44] which in the Commission's view—consistent with the commenter's view—includes ''inquiry regarding whether foreign requirements adequately reflect the interests and protections associated with the particular Title VII requirement.''[45] Also consistent with the commenter's view, the Commission's comparability assessments reflect a close reading of the relevant French and EU requirements. In addition, the Commission recognizes that other regulatory regimes will have exclusions, exceptions and exemptions that may not align perfectly with the corresponding requirements under the Exchange Act.[46] Accordingly, where French and EU requirements produce comparable outcomes—with or without conditions as discussed in part III.B below—notwithstanding those particular differences, and taking into account the scope and objectives and the effectiveness of supervision and enforcement of those requirements, the Commission has determined that the relevant French and EU requirements are comparable and has made a positive substituted compliance determination. Conversely, where those exclusions, exemptions and exceptions lead to outcomes that are not comparable—taking into account potential conditions—the Commission has not made a positive substituted compliance determination.

The Commission also is including certain conditions in the Order. The commenter stated that the inclusion of conditions should be viewed as an indication that the requirements of substituted compliance have not been met and as creating ''ad hoc, custom-made rules to supplement inadequate rules of other jurisdictions.''[47] Pursuant to rule 3a71–6, the Commission may make a conditional or unconditional substituted compliance determination.[48] As described in greater detail in part III.B below, many of the conditions in the Order are designed to make substituted compliance available to Covered Entities only when the relevant French and EU requirements in fact apply to the relevant security-based swap activity in a way that promotes comparable regulatory outcomes. The commenter correctly notes that the Order also employs conditions to promote comparability.[49] For example, substituted compliance in connection with Exchange Act rule 15Fi–3(c) dispute reporting provisions is conditioned in part on the Covered Entity providing the Commission with

[40] *See* Cross-Border Entity Definitions Adopting Release, 79 FR at 47292 (purposes of Title VII include consideration of risk to the U.S. financial system and promotion of transparency in the U.S. financial system); Exchange Act section 30(c), 15 U.S.C. 78dd(c) (Commission rulemaking authority to prevent evasion of Title VII); Exchange Act section 3(f), 15 U.S.C. 78c(f) (requirement to consider whether certain Commission rulemaking actions would promote efficiency, competition and capital formation); Exchange Act section 23(a)(2), 15 U.S.C. 78w(a)(2) (requirement to consider the impact of Exchange Act rules and regulations on competition and prohibition on adopting rules or regulations that would impose a burden on competition not necessary or appropriate in furtherance of the purposes of the Exchange Act); Dodd-Frank Act section 712(a)(2), 15 U.S.C. 8302 (requirement to consult and coordinate with U.S. financial regulatory authorities on Title VII rulemaking); Dodd-Frank Act section 752(a), 15 U.S.C. 8325 (requirement to consult and coordinate, as appropriate, with foreign regulatory authorities on the establishment of consistent international standards with respect to the regulation of security-based swaps and security-based swap entities); *see also* Exchange Act Release No. 77104 (Feb. 10, 2016), 81 FR 8598, 8599 (Feb. 19, 2016) (''ANE Adopting Release'') (''A key part of [the Title VII] framework is the regulation of security-based swap dealers, which may transact extensively with counterparties established or located in other jurisdictions and, in doing so, may conduct sales and trading activity in one jurisdiction and book the resulting transactions in another. These market realities and the potential impact that these activities may have on U.S. persons and potentially the U.S. financial system have informed our consideration of these rules.''); Exchange Act Release No. 87780 (Dec. 18, 2019), 85 FR 6270, 6272 and n.26 (Feb. 4, 2020) (''Cross-Border Adopting Release'') (''[T]he Title VII SBS Entity requirements . . . serve a number of regulatory purposes apart from mitigating counterparty and operational risks, 'including enhancing counterparty protections and market integrity, increasing transparency, and mitigating risk to participants in the financial markets and the U.S. financial system more broadly.' '' ''The Commission's actions to mitigate the negative consequences potentially associated with the various uses of [the 'arranged, negotiated or executed' test] accordingly are designed to do so while preserving the important Title VII interests that the Commission advanced when it incorporated the test into the various cross-border rules.'') (internal citations omitted).

[41] *See* Exchange Act Release No. 75611 (Aug. 5, 2015), 80 FR 48964, 48972–73 (Aug. 14, 2015) (''Registration Adopting Release'').

[42] *See id.*

[43] *See* Cross-Border Entity Definitions Adopting Release, 79 FR at 47286 n.65 (''Future rulemakings that depend on [the definitions of 'security-based swap dealer' and 'major security-based swap participant'] are intended to address the transparency, risk, and customer protection goals of Title VII.'').

[44] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85722; *see also* Business Conduct Adopting Release, 81 FR at 30076, 30078–79.

[45] *See* Business Conduct Adopting Release, 81 FR at 30067.

[46] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85722 n.17; *see also* Business Conduct Adopting Release, 81 FR at 30076, 30078–79.

[47] *See* Better Markets Letter at 4.

[48] *See* Exchange Act rule 3a71–6(a)(1).

[49] *See* Better Markets Letter at 2.

the dispute reports required under French law.[50] Consistent with rule 3a71–6, conditioning substituted compliance on the Commission receiving those reports helps to promote timely notice of disputes to support a comparable regulatory outcome.

3. Ensuring Ongoing Appropriateness of Substituted Compliance

One commenter stated that the Commission ''must ensure, on an ongoing basis, that each grant of substituted compliance remains appropriate over time.'' [51] The commenter added that substituted compliance orders and memoranda of understanding should incorporate the obligation that the Commission be apprised regarding the effectiveness of the jurisdiction's supervision and enforcement programs, and to immediately apprise the Commission of material changes to the regulatory regime.[52] The Commission concurs that the ongoing availability of substituted compliance should account for relevant changes in the foreign jurisdiction's regulatory requirements and in the effectiveness of that jurisdiction's supervisory and enforcement program.[53] Accordingly, the Commission and the French Authorities recently entered into a substituted compliance memorandum of understanding that addresses ongoing information regarding potential changes to substantive legal requirements and supervisory and enforcement effectiveness.[54] Additionally, the Commission and the ECB are in the process of developing a memorandum of understanding to address cooperation matters related to substituted compliance. The Commission believes that these arrangements will provide timely information to ensure that the Commission is aware of material developments that may affect the comparability of the relevant French and EU requirements, including the scope and objectives of those requirements and the effectiveness of the French Authorities' supervision and enforcement programs. In response to any such developments, the Commission may amend the Order as needed to ensure that it continues to require a Covered Entity to comply with comparable French and EU requirements, or may withdraw the Order if the relevant French or EU requirements are no longer comparable.[55] Moreover, substituted compliance under the Order is conditioned on the Commission having these memoranda of understanding, or another arrangement with the French Authorities and ECB addressing cooperation with respect to the Order, at the time the Covered Entity makes use of substituted compliance.[56] If the arrangements in the memoranda of understanding prove in practice not to provide information about relevant developments, the Commission could terminate the memoranda of understanding in accordance with its terms and/or amend or withdraw the Order.[57] If the Commission, the French Authorities or the ECB terminates either memorandum of understanding, Covered Entities would not be able to rely on substituted compliance under the Order to satisfy Exchange Act compliance obligations that arise after the termination takes effect. For these reasons, in the Commission's view, the Order's memoranda of understanding conditions, coupled with the ongoing information sharing provisions in the memoranda of understanding with the French Authorities and with the ECB, establish the commenter's suggested mechanism to apprise the Commission of changes that may affect the ongoing appropriateness of substituted compliance.

4. Request for Transition Period

Commenters stated that the Commission's proposed approach to certain entity-level requirements could result in the Commission's requirements still applying to a non-U.S. Entity's security-based swap transaction with non-U.S. counterparties and a resulting need for SBS Entities to obtain written agreement from their non-U.S. counterparties.[58] As a result, commenters requested a one-year transition period from the November 1, 2021, date by which security-based swap dealers must register with the Commission to come into compliance with any documentation requirements.[59]

The Commission is not providing an additional transition period at this time for documentation requirements related to Exchange Act requirements that will apply to Covered Entities' existing non-U.S. counterparties. The registration compliance date for U.S. and non-U.S. SBS Entities is October 6, 2021, and that is also the compliance date for the entity-level requirements at issue. These dates have been known to potential SBS Entities since February 4, 2020.[60] In areas where the Commission makes a positive substituted compliance determination under the Order, Covered Entities will have additional flexibility with respect to how to comply with the relevant Exchange Act requirements, but they, like all registered SBS Entities, must comply with the Exchange Act as of the registration compliance date. The Commission staff will be available to discuss implementation issues with Covered Entities during the implementation period.

III. General Availability of Substituted Compliance Under the Order

A. Covered Entities

1. Proposed Approach

Under the proposed Order, the definition of ''Covered Entity'' specified which entities could make use of substituted compliance. Consistent with the availability of substituted compliance under Exchange Act rule 3a71–6, the proposed definition in part would limit the availability of substituted compliance to registered SBS Entities that are not U.S. persons. In addition, to help ensure that firms that rely on substituted compliance are subject to relevant French and EU requirements and oversight, the proposed definition would require that Covered Entities be investment firms authorized to provide investment services by the AMF or credit institutions authorized by the ACPR after approval by the AMF of its program of operations to provide investment services or perform investment activities in France.[61]

[50] *See* para. (b)(3)(ii) of the Order.

[51] Better Markets Letter at 5.

[52] *Id.*

[53] *See* Business Conduct Adopting Release, 81 FR at 30078–79 (stating that order conditions and memoranda of understanding are possible tools for providing that the Commission be notified of material changes).

[54] The memorandum of understanding between the Commission and the French Authorities in part provides that the French Authorities will provide ''ongoing information sharing'' regarding Firm Information (incorporating supervisory and related information as to the Covered Entities using substituted compliance) and regarding Regulatory Change Information (incorporating information about any material publicly available draft, proposed, or final change in law, regulation, or order of the jurisdiction of the French Authorities that may have a material impact on the firms at issue with respect to their relevant activities). *See* note 17, *supra* (information on publication of memoranda of understanding with the French Authorities and ECB).

[55] Any such amendment or withdrawal may be at the Commission's own initiative after appropriate notice and opportunity for comment. *See* Exchange Act rule 3a71–6(a)(3).

[56] *See* part II.C.2, *supra;* paras. (a)(7) and (a)(8) of the Order.

[57] *See* note 18, *supra.*

[58] *See* SIFMA Letter I at 10; FBF Letter I at 3.

[59] *Id.*

[60] *See* Exchange Act Release No. 87780 (Dec. 18, 2019), 85 FR 6270 at 6345–46 (Feb. 4, 2020).

[61] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85723.

2. Commenter Views and Final Provisions

One commenter requested changes to the proposed ''Covered Entity'' definition, to reflect that under the French framework the requisite authorizations to provide credit and investment services are provided by the ACPR, in conjunction with the AMF's approval of the provision of investment services.[62] In addition, as described in the French Substituted Compliance Notice and Proposed Order, and confirmed by the AMF,[63] the AMF uses a risk-based approach to supervision whereby investment firms are categorized within four Tiers. Tier 1 firms receive the most supervisory attention and the staff has been told that all firms that use substituted compliance will be treated as Tier 1 firms.[64] The Commission has revised the Order in response to the comment and to reflect the AMF's approach.[65]

B. Additional General Conditions

1. Proposed Approach

The proposed Order incorporated a number of additional general conditions and other prerequisites, to help ensure that the relevant French and EU requirements that form the basis for substituted compliance in practice will apply to the Covered Entity's security-based swap business and activities, and to promote the Commission's oversight over entities that avail themselves of substituted compliance:

• *''Subject to and Complies with'' applicability condition*—For each relevant section of the proposed Order, a positive substituted compliance determination would be predicated on the entity being subject to and complying with the applicable French and EU requirements needed to establish comparability.[66]

• *MiFID ''investment services or activities''*—The Covered Entity's security-based swap activities would have to constitute ''investment services or activities'' for purposes of applicable provisions[67] under MiFID, MFC and related EU and French requirements, and must fall within the scope of the firm's authorization from the AMF or from the ACPR after approval by the AMF of the firm's program of operations.[68]

• *Counterparties as MiFID ''clients''*—The Covered Entity's counterparties (or potential counterparties) would have to be ''clients'' (or potential ''clients'') for purposes of MiFID, provisions under MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions.[69]

• *MiFID ''financial instruments''*—The relevant security-based swaps would have to be ''financial instruments'' for purposes of applicable provisions under MiFID, MFC and related EU and French requirements.[70]

• *CRD ''institutions''*—The Covered Entity would have to be an ''institution'' for purposes of applicable provisions under CRD, MFC, CRR and related EU and French requirements.[71]

• *Memoranda of understanding*—Consistent with the requirements of rule 3a71–6 and the Commission's need for access to information regarding registered entities, substituted compliance under the proposed Order would be conditioned on the Commission having applicable memoranda of understanding or other arrangements in place with the French Authorities and with the ECB, addressing cooperation with respect to the Order at the time the Covered Entity makes use of substituted compliance.[72]

• *Notice of reliance on substituted compliance*—To assist the Commission's oversight of firms that avail themselves of substituted compliance, a Covered Entity relying on the substituted compliance order would have to provide notice of its intent to rely on the Order by notifying the Commission in writing.[73]

When the Commission reopened the comment period and addressed the possible removal of certain MiFID-related conditions, the Commission also discussed the possibility of adding two new EMIR-related conditions related to ''counterparty'' status under EMIR and related to products subject to the European Market Infrastructure Regulation (''EMIR''), to satisfy the prerequisites to substituted

[62] *See* SIFMA Letter II at Appendix A.

[63] *See* Memorandum, dated June 10, 2021, from Patrice Aguesse of the French AMF.

[64] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85735.

[65] *See* para. (g)(1)(iii) of the Order (providing that a Covered Entity in part means ''an investment firm authorized by the ACPR to provide investment services or perform investment activities in the French Republic, or a credit institution authorized by the ACPR, after approval by the AMF of its program of operations to provide investment services or perform investment activities in the French Republic, and supervised by the AMF under its Tier 1 framework'').

[66] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85723. The Commission stated, as an example, that this proposed condition would not be satisfied when the comparable French or EU requirements would not apply to the security-based swap activities of a third-country branch of a French SBS Entity.

[67] Under this condition, a Covered Entity's security-based swap activities must constitute ''investment services or activities'' only to the extent that the relevant part of the Order requires the Covered Entity to be subject to and comply with a provision of MiFID, provisions under MFC that implement MiFID and related EU and French requirements. If the relevant part of the Order does not require the Covered Entity to be subject to and comply with one of those provisions, then the Covered Entity's security-based swap activities do not have to constitute ''investment services or activities'' to be able to use substituted compliance under that part of the Order.

[68] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85723. The EU's Markets in Financial Instruments Directive (''MiFID''), Directive 2014/65/EU, has been implemented in France as part of article L. 511 to the French Monetary and Financial Code—Code monétaire et financier (''MFC''). MiFID and MFC address, *inter alia,* organizational, compliance and conduct requirements applicable to nonbank ''investment firms.'' In significant part, those requirements also apply to credit institutions that provide investment services or perform investment activities. Commission Delegated Regulation (EU) 2017/565 (''MiFID Org Reg'') in part supplements MiFID with respect to organizational requirements for firms. The Markets in Financial Instruments Regulation (''MiFIR''), Regulation (EU) 648/2012, generally addresses trading venues and transparency. Commission Delegated Directive (EU) 2017/593 (''MiFID Delegated Directive'') in part supplements MiFID with regard to safeguarding client property, and in France is implemented in relevant part by the Règlement Général de L'Autorité des Marchés Financiers (''AMF General Regulation''). Directive (EU) 2015/849 (''MLD'') addresses requirements on the prevention of the use of the financial system for the purposes of money laundering or terrorist financing, and in France is implemented by article L. 561 to the MFC.

[69] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85723.

[70] *Id.*

[71] *Id.* The EU's Capital Requirements Directive IV (''CRD''), Directive 2013/36/EU has been adopted in France as part of article L. 533 to the MFC, and sets forth prudential requirements and certain related requirements applicable to credit institutions and certain nonbank investment firms. Certain CRD requirements regarding reporting obligations have been incorporated into French law as part of articles L. 511 and L. 634 to the MFC. The Capital Requirements Regulation (''CRR''), Regulation (EU) 575/2013, further addresses prudential requirements and related recordkeeping requirements for credit institutions and certain investment firms. Commission Implementing Regulation (EU) 680/2014 (''CRR Reporting ITS'') sets forth implementing technical standards regarding supervisory reporting. Pursuant to amendments that will become effective in June 2021, the requirements of CRD and the CRR will apply to credit institutions and to certain nonbank undertakings (that carry on activities involving dealing, portfolio management, investment advice and underwriting/placing) that meet specified thresholds (*e.g.,* consolidated assets of €30 billion or more). *See generally* Investment Firms Regulation (''IFR''), Regulation (EU) 2019/2033, art. 62 (amending certain definitions in the CRR).

[72] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85723. The Commission, AMF and ACPR have entered into a memorandum of understanding to address substituted compliance cooperation. The Commission and the ECB are also in the process of developing a memorandum of understanding or other arrangement to address cooperation matters related to substituted compliance. *See* notes 17–19, *supra.* Consistent with the Order, Covered Entities must ensure that this memorandum of understanding remains in place at the time the Covered Entity relies on substituted compliance.

[73] French Substituted Compliance Notice and Proposed Order, 85 FR at 85723.

compliance.[74] The Commission explained that those additional two conditions may ''promote certainty that EMIR will apply and help preclude gaps between the regulatory outcomes associated with the Exchange Act and those associated with the relevant EMIR provisions.'' [75] This is particularly significant due to the Order's removal of proposed MiFID-related conditions with respect to substituted compliance for trade acknowledgement and verification requirements and for trading relationship documentation requirements, and the accompanying heightened reliance on certain EMIR-related conditions.[76] The two additional EMIR-related conditions are:

• *Covered Entity's counterparties as EMIR ''counterparties''*—For each condition in the proposed Order that requires the application of, and compliance with, provisions of EMIR, Commission Delegated Regulation (EU) 149/2013 (''EMIR RTS'') and/or Delegated Regulation (EU) 2016/2251 (''EMIR Margin RTS''), if the counterparty to the Covered Entity is not a ''financial counterparty'' or ''non-financial counterparty'' as defined in EMIR articles 2(8) or 2(9), respectively, the Covered Entity must comply with the applicable condition as if the counterparty were a financial counterparty or non-financial counterparty. In other words, the Covered Entity would be subject to the relevant requirements under EMIR even if the counterparty is not authorized pursuant to EU law as anticipated by the EMIR article 2(8) ''financial counterparty'' definition, or if the counterparty is not an ''undertaking'' (such as by virtue of being a natural person), or is not established in the EU (by virtue of being a U.S. person or otherwise being established in some non-EU jurisdiction), as anticipated by the EMIR article 2(9) ''non-financial counterparty'' definition.[77]

• *Security-based swap status under EMIR*—For each condition in the proposed Order that requires the application of, and compliance with, provisions of EMIR, EMIR RTS and/or EMIR Margin RTS, either: (1) The relevant security-based swap must be an ''OTC derivative'' or ''OTC derivative contract,'' as defined in EMIR article 2(7), that has not been cleared by a central counterparty (''CCP'') and otherwise is subject to the provisions of EMIR; or (2) the relevant security-based swap must have been cleared by a central counterparty that has been authorized or recognized to clear derivatives contracts in the EU.[78]

2. Commenter Views and Final Provisions

Commenters addressed the proposed general conditions related to MiFID ''clients,'' the memoranda of understanding, and the notice to the Commission.[79] Commenters also addressed the two additional EMIR-related conditions the Commission discussed when it reopened the comment period.[80] For the reasons discussed below, the Order largely incorporates the general conditions as proposed, subject to certain changes and the addition of the two EMIR-related conditions.[81] In the Commission's view, the conditions are structured appropriately to predicate a positive substituted compliance determination on the applicability of relevant French and EU requirements needed to establish comparability, as well as on the continued effectiveness of the requisite MOU, and the provision of notice to the Commission regarding the Covered Entity's intent to rely on substituted compliance.

a. Counterparties as MiFID ''clients''

One commenter requested that the Commission modify the general condition regarding MiFID client status, which as proposed required that the counterparty be a ''client'' (or potential ''client'') as defined in MiFID, such that the condition also would encompass counterparties that are ''acting through an agent which the Covered Entity treats as its 'client' (or potential 'client').'' [82] The commenter stated that this change would address circumstances in which an agent acted on its counterparty's behalf, ''such as an investment manager acting for a fund,'' reasoning that in practice entities ''will look to the agent'' rather than the agent's principal when satisfying applicable requirements.[83]

As noted above, the proposed Order would require a Covered Entity to be ''subject to and comply with'' relevant MiFID-based requirements. The Commission proposed that requirement of the proposed Order to ensure that comparable MiFID-based requirements in practice would apply to a Covered Entity using substituted compliance. The condition in paragraph (a)(2) to the proposed Order would ensure that the Covered Entity's counterparty—*i.e.,* the entity to whom it owes its various duties under the Exchange Act—is the ''client'' to whom the Covered Entity owes its performance of the duties to which it is subject under the comparable MiFID-based requirements.[84] The Commission believes that, in the case of an agent acting on behalf of a principal, if the principal is the counterparty for purposes of the relevant Exchange Act requirement, then this condition should require the principal, as the counterparty, to be the ''client'' for purposes of the relevant MiFID-based requirements. If the Covered Entity instead treats the agent as the ''client,'' then the Covered Entity would not be ''subject to'' French and EU requirements that are comparable to Exchange Act requirements related to counterparties. Accordingly, the Commission is not amending the Order to modify the condition in paragraph (a)(2) to permit a Covered Entity to treat an agent, rather than the agent's principal, as its client with regard to the relevant MiFID-based requirements. In taking this position, the Commission does not prohibit Covered Entities from working with agents or others acting on behalf of a counterparty. Rather, the Covered Entity must ensure that, in working with the agent, it fulfills any duties owed to a ''client'' (or potential ''client'') in relation to the counterparty.[85]

[74] Reopening Release, 86 FR at 18342.

[75] *Id.*

[76] *See generally* parts IV.B.2 and IV.B.5 *infra.*

[77] *See* Reopening Release, 86 FR at 18342 n.9.

[78] *Id.* at 18342.

[79] *See* SIFMA Letter II at 7, 16, and Appendix A; FBF Letter II at 3 (addressing counterparties as MiFID ''clients''); Better Markets Letter at 5 (addressing the memorandum of understanding).

[80] *See* SIFMA Letter II at 4; FBF Letter II at 2; Better Markets Letter at 5–7.

[81] The Commission is adopting, largely as proposed, other general conditions that were not the subject of comments and that are not otherwise addressed below. *See* paras. (a)(1), (a)(3), and (a)(4) of the Order. The Commission is making technical changes to clarify the captions of certain of the general conditions (*e.g.,* in the final Order the caption to the proposed condition related to ''Activities as 'investment services or activities''' now refers to ''Activities as MiFID 'investment services or activities'''). Certain of the general conditions also have been renumbered from the proposal.

[82] SIFMA Letter II at Appendix A.

[83] SIFMA Letter II at 7.

[84] Some provisions of the MiFID-based requirements cited in the condition, such as certain organizational requirements, do not pertain to counterparties or clients. In those cases, there is no ''relevant counterparty (or potential counterparty)'' for purposes of the condition, and the condition would have no effect.

[85] MiFID article 26 permits firms to rely upon information about a client received from another French and EU-regulated firm. Under that provision, the other firm is legally responsible for the completeness and accuracy of any information about the client that the other firm receives from the first firm. The Commission believes that it is appropriate to permit a Covered Entity to rely on information about its client communicated by another French and EU-regulated firm on behalf of the client. Accordingly, the application of this provision would not cause the Covered Entity to be

b. Memoranda of Understanding

Commenters stated that a separate memorandum of understanding with the ECB need not be in place before SBS Entities can rely on the Order, based on the rationale that a memorandum of understanding containing certain assurances from the AMF and ACPR would be sufficient to ensure the Commission can promptly obtain relevant ECB-controlled information.[86] The Commission disagrees that such assurances would be sufficient. As the Order in part addresses substituted compliance for matters within the purview of the ECB, including but not limited to capital and margin requirements, the Commission believes that a memorandum of understanding with the ECB must be in place at the time an SBS Entity relies on the Order. As a result, the Order incorporates, as proposed, separate conditions related to the French Authorities and to the ECB memoranda of understanding.[87]

c. Notice of Reliance on Substituted Compliance

One commenter [88] requested that the Commission modify the proposed notice condition to correspond with the analogous condition that the Commission proposed in connection with the proposed substituted compliance order for the United Kingdom (UK).[89] The Commission agrees that the notice requirements for the substituted compliance orders should be consistent. As a result, the condition has been modified from the French proposed Order to add flexibility by stating that the notice must be sent to the Commission in the manner specified on the Commission's website (while the proposed Order instead referred to an email address).[90] Moreover, the condition further has been modified from the proposal by stating that the notice must identify each specific substituted compliance determination for which the Covered Entity intends to apply substituted compliance.[91] Further, a Covered Entity must promptly update the notice if it intends to modify its reliance on the positive substituted compliance determinations in the Order.[92] Every SBS Entity registered with the Commission, whether complying directly with Exchange Act requirements or relying on substituted compliance as a means of complying with the Exchange Act, is required to satisfy the inspection and production requirements imposed on such entities under the Exchange Act,[93] and specificity as to the scope of the entity's reliance on substituted compliance is necessary to facilitate the Commission's oversight under the Order.

d. Additional EMIR-Related Conditions

The final rules have been modified from the proposal to add two general conditions that address Covered Entities' reliance on the EMIR-related provisions. The additions should help ensure that the relevant EMIR-related provisions will apply in fact, and help avoid any gaps between the regulatory outcomes associated with Exchange Act requirements and regulatory outcomes associated with those EMIR-related provisions. Consistent with the discussion regarding scope of substituted compliance in part II.B, in the context of the EMIR counterparties condition in paragraph (a)(5), a Covered Entity must choose (1) to apply substituted compliance pursuant to the Order—including compliance with paragraph (a)(5) as applicable—for a particular set of entity-level requirements with respect to all of its business that would be subject to the relevant EMIR-based requirement if the counterparty were the relevant type of counterparty, or (2) to comply directly with the Exchange Act with respect to such business.

Some commenters expressed general support for adding the two additional EMIR-related general conditions to the Order.[94] One commenter disagreed with including any additional EMIR-related conditions, expressing the view that if ''some industry participants may not be able to take advantage of substituted compliance under the SEC's proposed framework is not, in and of itself, a reason to change the framework.'' [95]

The first new general condition addresses the fact that the ''financial counterparty'' and ''non-financial counterparty'' definitions that trigger the application of the relevant EMIR provisions are predicated on the entity being an undertaking established in the

not ''subject to'' the relevant French and EU requirements listed in the Order, and thus would not impact the Covered Entity's ability to use substituted compliance in relation to those communications. On the other hand, MiFID article 26 also provides that the other firm is legally responsible for the suitability of advice and recommendations provided to the client. The other firm, however, may not be a Covered Entity applying substituted compliance pursuant to the Order. Accordingly, the Commission believes that a Covered Entity relying on the suitability assessment of another firm pursuant to MiFID article 26 is not ''subject to'' the relevant French suitability requirements listed in the Order, and thus may not apply substituted compliance for those recommendations.

[86] *See* SIFMA Letter I at 16; *see also* FBF Letter I at 3.

[87] *See* paras. (a)(7) and (a)(8) of the Order.

[88] SIFMA Letter II at Appendix A.

[89] Exchange Act Release No. 91476 (Apr. 5, 2021), 86 FR 18378 (Apr. 8, 2021) (''UK Proposed Order'').

[90] *See* para. (a)(9) of the proposed Order.

[91] *See* para. (a)(9) of the Order. If the Covered Entity intends to rely on all the substituted compliance determinations in a given paragraph of the Order, it can cite that paragraph in the notice. For example, if the Covered Entity intends to rely on the capital and margin determinations in paragraph (c) of the Order, it can indicate in the notice that it is relying on the determinations in paragraph (c). However, if the Covered Entity intends to rely on the margin determination but not the capital determination, it will need to indicate in the notice that it is relying on paragraph (c)(2) of the Order (the margin determination). In this case, paragraph (c)(1) of the Order (the capital determination) will be excluded from the notice and the Covered Entity will need to comply with the Exchange Act capital requirements. Further, as discussed below, the recordkeeping and reporting determinations in the Order have been structured to provide Covered Entities with a high level of flexibility in selecting specific requirements within those rules for which they want to rely on substituted compliance. For example, paragraph (f)(1)(i) of the Order sets forth the Commission's substituted compliance determinations with respect to the requirements of Exchange Act rule 18a–5, 17 CFR 240.18a–5. These determinations are set forth in paragraphs (f)(1)(i)(A) through (O) of the Order. If a Covered Entity intends to rely on some but not all of the determinations, it will need to identify in the notice the specific determinations in this paragraph it intends to rely on (*e.g.,* paragraphs (f)(1)(i)(A), (B), (C), (D), (G), (H), (I), and (O)). For any determinations excluded from the notice, the Covered Entity will need to comply with the Exchange Act rule 18a–5 requirement. Finally, a Covered Entity is able to apply substituted compliance at the transaction level (rather than the entity level) for certain counterparty protection requirements and the recordkeeping requirements that are linked to them. In this case, the notice will need to indicate the class of transactions (*e.g.,* transactions with French counterparties) for which the Covered Entity is applying substituted compliance with respect to the Exchange Act counterparty protection requirements and linked recordkeeping requirements. Similarly, as discussed above, a Covered Entity is able to apply substituted compliance for entity-level Exchange Act requirements to all of its security-based swap business that is eligible for substituted compliance under the Order, and may either comply directly with the Exchange Act or apply substituted compliance under another applicable order for its security-based swap business that is not eligible for substituted compliance under the Order. In this case, the notice will need to indicate the scope of security-based swap business (*e.g.,* security-based swap business carried on from an establishment in France) for which the Covered Entity is applying substituted compliance with respect to the relevant Exchange Act entity-level requirements.

[92] A Covered Entity would modify its reliance on the positive substituted compliance determinations in the Order, and thereby trigger the requirement to update its notice, if it adds or subtracts determinations for which it is applying substituted compliance or completely discontinues its reliance on the Order.

[93] *See* French Substituted Compliance Notice and Proposed Order, 85 FR 85734.

[94] *See* FBF Letter II at 2 (stating that ''[t]he FBF is generally welcoming of the new general EMIR conditions that are introduced as a corollary to the above changes. As applied in the context of trading relationship documentation, trade acknowledgment and verification, they largely convey the manner in which EMIR has been interpreted.''); *see also* SIFMA Letter II at 4.

[95] Better Markets Letter at 6.

EU.[96] The conditions are not based upon the concern that some industry participants may not be able to take advantage of substituted compliance, but rather the conditions are intended to help ensure that the relevant EMIR requirements will apply in practice regardless of the counterparty's location or status as ''an undertaking''. As such, the condition provides that the Covered Entity must comply with the applicable condition of this Order as if the counterparty were the type of counterparty that would trigger the application of the relevant EMIR-based requirements. If the Covered Entity reasonably determines that its counterparty would be a financial counterparty if not for the counterparty's location and/or lack of authorization in the EU, the condition further requires the Covered Entity to treat the counterparty as if the counterparty were a financial counterparty, rather than as another type of counterparty to which the relevant EMIR-based requirements apply.[97] By requiring a Covered Entity to treat its counterparty as the type of counterparty that would trigger the application of the relevant EMIR-based requirements, the EMIR-based requirements require the Covered Entity to act in a way that is comparable to Exchange Act requirements. The Commission is modifying the Order to include this condition to ensure that a Covered Entity can apply substituted compliance only when it treats its counterparty as a type that will trigger the Covered Entity's performance of obligations pursuant to those EMIR-based requirements.[98] Because each EMIR-based requirement applies to different types of counterparties, the Commission is amending the condition to make clear that a Covered Entity must treat its counterparty as if the counterparty were the type of counterparty specified in the relevant EMIR-based requirement and that a Covered Entity may not rely on EMIR article 13 to comply with another jurisdiction's requirement.

Another commenter requested that the Commission clarify that this condition would not require a Covered Entity to treat as financial counterparties or non-financial counterparties certain public sector counterparties, such as multilateral development banks, that are exempt from EMIR or counterparties that are not ''undertakings'' for purposes of EMIR's definitions of ''financial counterparty'' and ''non-financial counterparty.''[99] The Commission declines to do so, given that the relevant requirements under the Exchange Act lack analogous carve-outs based on counterparty status. The Commission is, however, clarifying that the condition applies only if the relevant EMIR-based provision applies to the Covered Entity's activities with specified types of counterparties.[100]

The second new general condition accounts for the fact that: (a) The relevant trade acknowledgement and verification and trading relationship documentation rules under the Exchange Act do not apply to security-based swaps cleared by a clearing agency registered with the Commission or a clearing agency that is exempt from registration with the Commission, and (b) the analogous EMIR provisions only apply to over-the-counter derivatives that are not cleared on a CCP (as defined in EMIR article 2(1)). To help ensure that substituted compliance is not precluded in connection with instruments that have been cleared in the EU, this second condition provides that for the applicable EMIR-related conditions, the relevant security-based swap must be an ''OTC derivative'' or ''OTC derivative contract'' (as defined under EMIR) that has not been cleared and otherwise is subject to the provisions of the relevant requirements under EMIR, or else that the relevant security-based swap must have been cleared by a central counterparty that has been authorized or recognized by a relevant authority to clear derivatives contracts in the EU.[101]

One commenter requested that the second new general condition be revised to include transactions cleared by *any* central counterparty—not merely central counterparties authorized or recognized by the EU.[102] The commenter stated that in certain circumstances French and EU law permit counterparties to agree to submit certain transactions to third-country central counterparties, and that it would be impractical to require Covered Entities to satisfy Exchange Act requirements that are ''principally targeted to non-cleared [security-based swaps] in relation to these transactions.''[103] The Commission has modified the condition to clarify that it extends to instruments cleared by central counterparties that have been authorized or recognized by a ''relevant authority'' in the EU, but the Commission declines to extend it to instruments cleared on ''any'' central counterparty, as such a standard would provide no safeguard against the risks potentially associated with central counterparties that are not subject to adequate safeguards. In application, the central counterparties described by the provision would extend to those that have been authorized by a competent authority pursuant to EMIR article 14, and those that have been recognized by the European Securities and Markets Authority (''ESMA'') pursuant to EMIR article 25.[104]

Finally, the Commission is amending the condition to clarify that the condition applies only if the relevant EMIR-based provision applies to OTC derivatives that have not been cleared by a central counterparty, as some provisions of EMIR cited in the Order, such as EMIR articles 39(4) and (5), are not limited in their application to non-centrally cleared OTC derivatives. Consistent with the condition in paragraph (a)(6) of the Order, the Commission is also adding to the condition references to EMIR RTS and EMIR Margin RTS.

e. Notification Requirements Related to Changes in Capital

A commenter requested that the Commission make more granular substituted compliance determinations with respect to the Exchange Act recordkeeping requirements.[105] The commenter stated that for ''operational reasons'' a Covered Entity may ''prefer to comply directly with certain Exchange Act requirements (*i.e.,* not to rely on substituted compliance with those requirements).''[106] The Commission took this approach in the UK Proposed Order with respect to the Exchange Act recordkeeping, reporting, and notification requirements.[107] As

[96] *See* EMIR articles 2(8) and 2(9).

[97] EMIR article 2(8) defines ''financial counterparty'' to encompass investment firms, credit institutions, insurers and certain other types of businesses that have been authorized in accordance with EU directives. The distinction between ''financial'' and ''non-financial'' counterparties under EMIR is manifested, *inter alia,* in connection with confirmation timing standards (*see* EMIR RTS article 12).

[98] *See* para. (a)(5) of the Order.

[99] SIFMA Letter II at 4.

[100] *See* para. (a)(5) of the Order.

[101] *See* para. (a)(6) of the Order. Absent this type of condition, instruments that have been cleared at an EU-authorized or recognized central counterparty neither would be excluded from the application of those Exchange Act rules nor would be subject to the EMIR requirements that otherwise would underpin substituted compliance. That would make direct compliance with the Exchange Act rules problematic, but compliance with the conditions of a positive substituted compliance order unworkable.

[102] SIFMA Letter II at 4–5.

[103] *Id.* at 4.

[104] In light of these considerations, the condition does not extend to clearing permitted pursuant to the equivalence framework of EMIR article 13.

[105] *See* SIFMA Letter I at 8.

[106] *Id.*

[107] *See* UK Substituted Compliance Notice and Proposed Order, 86 FR 18394–403, 18415–420.

part of this approach, the Commission also conditioned substituted compliance with certain of the discrete recordkeeping, reporting, and notification requirements on the Covered Entity applying substituted compliance with respect to the substantive Exchange Act requirement to which they were linked.[108] This linked condition was designed to ensure that a Covered Entity consistently applies substituted compliance with respect to the substantive Exchange Act requirement and the Exchange Act recordkeeping, reporting, or notification requirement that complements the substantive requirement. The Commission sought comment in the Reopening Release on whether it should take a similar granular approach to the Exchange Act recordkeeping, reporting, and notification requirements.[109]

On further consideration and in light of the more granular approach requested by the commenter, the Commission believes it necessary to do the reverse with respect to certain substantive financial responsibility requirements: Condition substituted compliance with respect to the substantive requirement on the Covered Entity applying substituted compliance with respect to the linked recordkeeping, reporting, or notification requirement. The Exchange Act financial responsibility requirements addressed in this Order (capital, margin, recordkeeping, reporting, notification, and securities count requirements) are highly integrated. Therefore, implementing the reverse conditional link is designed to ensure that the granular approach requested by the commenter results in comparable regulatory outcomes in terms of obligations to make and preserve records, and to submit reports and notifications to the Commission concerning the Covered Entity's compliance with the financial responsibility rules. It also is designed to provide clarity as to the obligations of a Covered Entity under this Order when using the granular approach to the Exchange Act recordkeeping, reporting, and notification requirements linked to the financial responsibility rules.

For example, because of the granular approach, a Covered Entity could elect to apply substituted compliance with respect to a substantive Exchange Act requirement such as the capital requirements of Exchange Act rule 18a–1 but elect not to apply substituted compliance with respect to a linked requirement under Exchange Act rule 18a–8 to provide the Commission notice of a capital deficiency under Exchange Act rule 18a–1. In this scenario, the Covered Entity would not be subject to the condition for applying substituted compliance with respect to Exchange Act rule 18a–8; namely, that the firm provide the Commission copies of notifications relating to French and EU capital requirements required under French and EU law. Consequently, as discussed below in this section and other sections of this release, the Commission is conditioning substituted compliance with respect to certain substantive Exchange Act requirements on the Covered Entity applying substituted compliance with respect to linked recordkeeping reporting, or notification requirements.

Exchange Act Rule 18a–8(c)

Exchange Act rule 18a–8(c) generally requires every security-based swap dealer with a prudential regulator that files a notice of adjustment of its reported capital category with the Federal Reserve Board, the Office of the Comptroller of the Currency, or the Federal Deposit Insurance Corporation to give notice of this fact that same day by transmitting a copy of the notice of adjustment of reported capital category in accordance with Exchange Act rule 18a–8(h).[110] Exchange Act rule 18a–8(h) sets forth the manner in which every notice or report required to be given or transmitted pursuant to Exchange Act rule 18a–8 must be made.[111] While Exchange Act rule 18a–8(c) is not linked to a substantive Exchange Act requirement, it is linked to substantive capital requirements applicable to prudentially regulated SBS Entities in the U.S. (*i.e.,* capital requirements of the Federal Reserve Board, the Office of the Comptroller of the Currency, or the Federal Deposit Insurance Corporation). Therefore, to implement the granular approach requested by the commenter, the Commission is adding a general condition that Covered Entities with a prudential regulator relying on the final Order for substituted compliance must apply substituted compliance with respect to the requirements of Exchange Act rule 18a–8(c) and the requirements of Exchange Act rule 18a–8(h) as applied to Exchange Act rule (c).[112]

In their application, the French Authorities cited several French provisions as providing similar outcomes to the notifications requirements of Exchange Act rule 18a–8. Additionally, based on comments received, the Commission has identified additional provisions that are relevant.[113] This general condition is necessary in order to clarify that a prudentially regulated Covered Entity must provide the Commission with copies of any notifications regarding changes in the Covered Entity's capital situation required by French and EU law. In particular, a prudentially regulated Covered Entity could elect not to apply substituted compliance with respect to Exchange Act rule 18a–8(c). However, because the Covered Entity is not required to provide any notifications to the Federal Reserve Board, the Office of the Comptroller of the Currency, or the Federal Deposit Insurance Corporation, ''compliance'' with the provisions of Exchange Act rule 18a–8(c) raises a question as to the Covered Entity's obligations under this Order to provide the Commission with notification of changes in capital.

Moreover, a commenter stated that foreign financial services firms were among the entities that used emergency lending facilities in the U.S. along with other U.S. measures to address the 2008 financial crisis.[114] The Commission adopted Exchange Act rule 18a–8(c) to require SBS Entities with a prudential regulator to give notice to the Commission when filing an adjustment of reported capital category because such notices may indicate that the entity is in or is approaching financial difficulty.[115] The Commission has a regulatory interest in being notified of changes in the capital of a prudentially regulated Covered Entity, as it could signal the firm is in or approaching financial difficulty and presents a risk to U.S. security-based swap markets and participants. For the foregoing reasons, the Commission is conditioning applying substituted compliance pursuant to the Order on the general condition that a prudentially regulated Covered Entity apply substituted compliance with respect to Exchange Act rule 18a–8(c) and the requirements

[108] *Id.*

[109] *See* Reopening Release, 86 FR at 18347–48.

[110] *See* 17 CFR 240.18a–8(c).

[111] *See* 17 CFR 240.18a–8(h).

[112] Better Markets Letter at 2–3.

[113] These French provisions include: (1) MFC Articles L. 511–33II, L. 634–1, and L. 634–2, which provide, among other things, that the staff of firms may report potential or actual breaches related to certain specified provisions, and provide for the establishment of procedures and secure communication channels through which French regulatory and prudential authorities can be informed of failures to comply with applicable regulations; and (2) Internal Control Order articles 249 and 249–1, which require notification to the ACPR, without delay, of significant incidents with respect to certain thresholds related to the firm's risk analysis and measurement systems, and with respect to operational incidents.

[114] Better Markets Letter at 2.

[115] *See* Exchange Act Release No. 71958 (Sept. 19, 2019), 84 FR 68550, 68589–90 (Dec. 16, 2019) (''Recordkeeping and Reporting Adopting Release'') (citing Exchange Act Release No. 71958 (Aug. 17, 2014) 79 FR 25193, 25249 (May 2, 2014)).

of Exchange Act rule 18a–8(h) as applied to Exchange Act rule 18a–8(c).

C. European Union Cross-Border Matters

1. Proposed Approach

The proposed Order also included general conditions to address the cross-border application of MiFID and MAR, along with EU and French requirements adopted pursuant to those directives. For some requirements under MiFID (and other EU and Member State requirements adopted pursuant to MiFID), EU law allocates the responsibility for supervising and enforcing those requirements to authorities of the Member State where an entity provides certain services. Similarly, for some requirements under MAR (and other EU and Member State requirements adopted pursuant to MAR), EU law allocates the responsibility for supervising and enforcing those requirements to authorities of potentially multiple Member States. To help ensure that the prerequisites to substituted compliance with respect to supervision and enforcement are satisfied in fact, the proposed Order provided substituted compliance only if one of the authorities responsible for supervision and enforcement of those requirements is the AMF or the ACPR.[116]

2. Commenter Views and Final Provisions

Commenters raised concerns with the proposed approach to European Union cross-border matters. The commenters did not object to the Commission's underlying premise, with one commenter noting that they ''[understood] that the Commission has included these conditions in the order to ensure that the prerequisites with respect to supervision and enforcement are satisfied.'' [117] Commenters instead asserted that the proposed condition would significantly curtail the ability to rely on the Order, with one commenter stating that requiring the AMF or ACPR to be allocated responsibility for the supervision and enforcement of applicable MiFID and MAR provisions, ''will in practice lead to an untenable patchwork of substituted compliance.'' [118] To address these issues, commenters urged the Commission to consider whether it could dispense with certain of the requirements cited in the proposed Order and still make a holistic, outcomes based comparability determination.

The Commission continues to believe that requiring that the AMF or ACPR have responsibility for applicable MiFID and MAR provisions will help ensure that the supervision and enforcement prerequisites to substituted compliance are satisfied.[119] Additionally, the proposed approach helps ensure that applicable MiFID and MAR provisions are interpreted and applied in a consistent manner by entities that are party to the MOUs and/or other arrangements which are a prerequisite to substituted compliance.[120] In light of these considerations the Commission is issuing the general conditions related to EU cross-border matters largely as proposed.[121] In the Commission's view, these conditions are structured appropriately to permit the use of substituted compliance only when the AMF or the ACPR is the entity responsible for supervising a Covered Entity's compliance with a relevant provision of MiFID, MAR or related EU or French requirements.

The Commission agrees, however, that in light of the EU cross-border implications, further consideration of the specific conditions cited with respect to internal risk management, trade acknowledgement and verification, trading relationship documentation, internal supervision and compliance and recordkeeping, reporting, notification, and securities counts is warranted to ensure that the scope of substituted compliance is appropriate. The Commission addresses those specific requirements below.[122]

This part of the Order has been modified from the proposed Order to incorporate references to conditions requiring compliance with MiFIR, given that certain relevant MiFIR conditions to substituted compliance are subject to the same principles regarding the allocation of authority.[123]

IV. Substituted Compliance for Risk Control Requirements

A. Proposed Approach

The French Authorities' Application in part requested substituted compliance in connection with risk control requirements relating to:

- Internal risk management—Internal risk management system requirements that address the obligation of registered entities to follow policies and procedures reasonably designed to help manage the risks associated with their business activities.
- Trade acknowledgment and verification—Trade acknowledgment and verification requirements intended to help avoid legal and operational risks by requiring definitive written records of transactions and procedures to avoid disagreements regarding the meaning of transaction terms.
- Portfolio reconciliation and dispute reporting—Portfolio reconciliation and dispute reporting provisions that require that counterparties engage in portfolio reconciliation and resolve discrepancies in connection with uncleared security-based swaps, and to provide prompt notification to the Commission and applicable prudential regulators regarding certain valuation disputes.
- Portfolio compression—Portfolio compression provisions that require that SBS Entities have procedures addressing bilateral offset, bilateral compression and multilateral compression in connection with uncleared security-based swaps.
- Trading relationship documentation—Trading relationship documentation provisions that require SBS Entities to have procedures to execute written security-based swap trading relationship documentation with their counterparties prior to, or contemporaneously with, executing certain security-based swaps.[124]

Taken as a whole, these risk control requirements help to promote market stability by mandating that registered entities follow practices that are appropriate to manage the market, counterparty, operational, and legal risks associated with their security-based swap businesses.

In considering conditional substituted compliance for the risk control portion of the French Authorities' Application, the Commission preliminarily concluded that the relevant French and EU requirements generally would help to produce regulatory outcomes that are comparable to those under the Exchange Act by subjecting Covered Entities to risk mitigation and documentation practices that are appropriate to the risks associated with their security-based swap businesses.[125] Substituted compliance under the proposed Order was to be conditioned in part on Covered Entities being subject to and

[116] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85724, 85739.

[117] *See* SIFMA Letter I at 2–8.

[118] *See* SIFMA Letter I at 3.

[119] *See* Business Conduct Adopting Release, 81 FR at 30080; *see also id.* at 30067.

[120] *See id.* at 30087.

[121] *See* para. (a)(8) of the Order.

[122] *See also* discussion in part III.B.2.d.

[123] MiFID article 35(8) particularly provides that these allocation principles apply in connection with MiFIR articles 14 to 26. The Commission requested comment on the addition of MiFIR and received no comment.

[124] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85724.

[125] *Id.* at 85724.

complying with the specified French and EU provisions that in the aggregate help to produce regulatory outcomes that are comparable to those associated with the risk control requirements under the Exchange Act.[126]

Substituted compliance under the proposed Order also was to be subject to certain additional conditions to help ensure the comparability of outcomes: (a) Substituted compliance in connection with the trading relationship documentation provisions would be conditioned on the requirement that the Covered Entity not treat its counterparties as ''eligible counterparties'' for purposes of relevant MiFID provisions;[127] (b) substituted compliance related to trading relationship documentation under the proposed Order would not extend to certain disclosures regarding legal and bankruptcy status;[128] and (c) substituted compliance in connection with portfolio reconciliation and dispute reporting requirements would be conditioned on the Covered Entity having to provide the Commission with reports regarding disputes between counterparties on the same basis as they provide those reports to competent authorities pursuant to EU law.[129]

B. Commenter Views and Final Provisions

Commenters initially expressed the view that the Commission should modify certain of the proposed conditions related to substituted compliance in connection with internal risk management, trade acknowledgement and verification, and trading relationship documentation requirements.[130] Specifically, commenters expressed concerns with proposed MiFID requirements for trade acknowledgement and verification and trading relationship documentation that ''cover the same ground'' as proposed EMIR requirements and ''would result in undue burdens for French [security-based swap dealers].''[131] Partially in light of those concerns, the Commission reopened the comment period and solicited additional comment on whether EMIR requirements standing alone could produce comparable results such that certain MiFID provisions may be removed as prerequisites to substituted compliance for trade acknowledgement and verification and trading relationship documentation requirements.[132] Certain commenters generally supported changes contemplated by the Commission in the Reopening Release.[133] Another commenter stated that French and EU requirements are not sufficiently comparable to Exchange Act requirements.[134]

After considering commenters' recommendations regarding the risk control requirements, the Commission is making positive substituted compliance determinations in connection with internal risk management, trade acknowledgment and verification, portfolio reconciliation and dispute reporting, portfolio compression and trading relationship documentation requirements. As discussed below, the final Order has been changed from the proposed Order in certain respects in response to comments following the proposed Order and Reopening Release. The Commission continues to conclude that, taken as a whole, applicable requirements under French and EU law subject Covered Entities to risk mitigation and documentation practices that are appropriate to the risks associated with their security-based swap businesses, and thus help to produce regulatory outcomes that are comparable to the outcomes associated with the relevant risk control requirements under the Exchange Act. Although the Commission recognizes that there are differences between the approaches taken by the relevant risk control requirements under the Exchange Act and relevant French and EU requirements, the Commission continues to believe that those differences on balance should not preclude substituted compliance for these requirements, as the relevant French and EU requirements taken as a whole help to produce comparable regulatory outcomes.

To help ensure the comparability of outcomes, substituted compliance for risk control requirements is subject to certain conditions. Substituted compliance for internal risk management, trade acknowledgment and verification, portfolio reconciliation and dispute reporting, portfolio compression and trading relationship documentation requirements is conditioned on the Covered Entity being subject to, and complying with, relevant French and EU requirements.[135] In addition, consistent with the proposed Order, substituted compliance for trading relationship documentation does not extend to disclosures regarding legal and bankruptcy status that are required by Exchange Act rule 15Fi–5(b)(5) when the counterparty is a U.S. person.[136] Finally, consistent with the proposed Order, substituted compliance for portfolio reconciliation and dispute reporting requirements is conditioned on the Covered Entity providing the Commission with reports regarding disputes between counterparties on the same basis as the Covered Entity provides those reports to its competent authority pursuant to French and EU

[126] *Id.* at 85724 n.37.

[127] *Id.* at 85725. Certain relevant French and EU requirements that provide for this type of documentation do not apply to investment firms' transactions with ''eligible counterparties.''

[128] *Id.* The trading relationship documentation provisions of rule 15F(b)(5) require certain disclosures regarding the status of the SBS Entity or its counterparty as an insured depository institution or financial counterparty, and regarding the possible application of the insolvency regime set forth under Title II of the Dodd-Frank Act or the Federal Deposit Insurance Act. Documentation requirements under applicable French and EU law would not be expected to address the disclosure of information related to insolvency procedures under U.S. law.

[129] *Id.* Under the Exchange Act requirement, SBS Entities must promptly report, to the Commission, valuation disputes in excess of $20 million that have been outstanding for three or five business days (depending on counterparty types). EU requirements provide that firms must report at least monthly, to competent authorities, disputes between counterparties in excess of €15 million and outstanding for at least 15 business days.

[130] *See* SIFMA Letter I at 4–6; FBF Letter I at 2.

[131] *See* FBF Letter I at 2. *See also* SIFMA Letter I at 3 (noting that the application of certain proposed MiFID and EMIR rules would ''lead to an untenable patchwork of substituted compliance.'')

[132] *See* Reopening Release, 86 FR at 18343.

[133] *See* SIFMA Letter II at 6 (stating that ''[w]e generally support these proposed modifications to the French Order''); *see also* FBF Letter II at 2. *But see* Better Markets Letter at 6 (''It is understandable that industry groups would urge the SEC to make it easier for more members of the industry to avail themselves of the privilege of substituted compliance . . . . However, easing regulatory burdens for the industry is not the SEC's job.'').

[134] *See* Better Markets Letter at 1–2.

[135] *See* paras. (b)(1) through (5) of the Order.

[136] *See* para. (b)(5) of the Order. The Exchange Act rule 15Fi–5, 17 CFR 240.15Fi–5, disclosures address information regarding: (1) The status of the SBS Entity or its counterparty as an insured depository institution or financial counterparty, and (2) the possibility that in certain circumstances the SBS Entity or its counterparty may be subject to the insolvency regime set forth in Title II of the Dodd-Frank Wall Street Reform and Consumer Protection Act or the Federal Deposit Insurance Act, which may affect rights to terminate, liquidate or net security-based swaps. *See* Exchange Act Release No. 87782 (Dec. 18, 2019), 85 FR 6359, 6374 (Feb. 4, 2020) (''Risk Mitigation Adopting Release''). Documentation requirements under applicable French and EU law do not address the disclosure of information related to insolvency procedures under U.S. law. However, the absence of such disclosures would not appear to preclude a comparable regulatory outcome when the counterparty is not a U.S. person, as the insolvency-related consequences that are the subject of the disclosure would not apply to non-U.S. counterparties in most cases. Moreover, EMIR Margin RTS article 2 requires counterparties to establish, apply and document risk management procedures providing for or specifying the terms of agreements entered into by the counterparties, including applicable governing law for non-centrally cleared derivatives. When counterparties enter into a netting or collateral exchange agreement, they also must perform an independent legal review of the enforceability of those agreements.

law.[137] A Covered Entity that is unable to comply with an applicable condition—and thus is not eligible to use substituted compliance for the particular set of Exchange Act risk control requirements related to that condition—nevertheless may use substituted compliance for another set of Exchange Act requirements addressed in the Order if it complies with the conditions to the relevant parts of the Order.

Under the Order, substituted compliance for risk control requirements (relating to internal risk management, trade acknowledgment and verification, portfolio reconciliation and dispute reporting, portfolio compression and trading relationship documentation) is not subject to a condition that the Covered Entity apply substituted compliance for related recordkeeping requirements in Exchange Act rules 18a–5 and 18a–6. A Covered Entity that applies substituted compliance for one or more risk control requirements, but does not apply substituted compliance for the related recordkeeping requirements in Exchange Act rules 18a–5 and 18a–6, will remain subject to the relevant provisions of Exchange Act rules 18a–5 and 18a–6. Those rules require the Covered Entity to make and preserve records of its compliance with Exchange Act risk control requirements and of its security-based swap activities required or governed by those requirements. A Covered Entity that applies substituted compliance for a risk control requirement, but complies directly with related recordkeeping requirements in rules 18a–5 and 18a–6, therefore must make and preserve records of its compliance with the relevant conditions of the Order and of its security-based swap activities required or governed by those conditions and/or referenced in the relevant parts of rules 18a–5 and 18a–6.

1. Internal Risk Management

Exchange Act section 15F(j)(2) requires a registered SBS Entity to establish robust and professional risk management systems adequate for managing its day-to-day business. In addition, Exchange Act rule 15Fh–3(h)(2)(iii)(I) requires an SBS Entity to establish and maintain a system to supervise, and to diligently supervise, its business and the activities of its associated persons. This system of internal supervision must include, in relevant part, the establishment, maintenance and enforcement of written policies and procedures reasonably designed, taking into consideration the nature of the SBS Entity's business, to comply with its duty under Exchange Act section 15F(j)(2) to establish an internal risk management system.

Under the proposed Order, substituted compliance in connection with internal risk management requirements would have been conditioned on Covered Entities being subject to and complying with certain MiFID, CRD and EMIR requirements related to internal risk management. One commenter expressed the view that the scope of this proposed condition would require SBS Entities to be subject to and comply with ''an expansive range of detailed and prescriptive requirements'' that are not necessary to produce comparable regulatory outcomes.[138] The commenter further criticized conditions requiring compliance with certain internal risk management requirements prescribed by the CRD, stating that those prescriptive requirements go beyond the ''high-level'' internal risk management requirements set forth by Exchange Act section 15F(j)(2).[139] The commenter also expressed the view that the conditions should not extend to the compliance system requirements of MiFID Org Reg article 22, on the grounds that compliance system requirements do not relate to risk management.[140] Commenters reiterated these same concerns following the reopening of the comment period, requesting the removal of specific MiFID, MFC, MiFID Org Reg, CRD, CRR, Prudential Supervision and Risk Assessment Order, and EMIR Margin RTS requirements for internal risk management.[141] By contrast, another commenter requested that the Commission ''not weaken [the risk control] conditions any further.'' [142]

The proposed Order included CRD articles 79 through 87, MiFID articles 16(4) and (5), CRR articles 286 through 288 and 293, EMIR Margin RTS article 2, MiFID Org Reg articles 21, 22 and 24, and the implementing provisions of French law. A commenter stated that the Commission should delete those provisions because they do not correspond to and go beyond Exchange Act internal risk management requirements.[143] However:

- CRD article 79 and the implementing provisions of French law address a Covered Entity's management of credit and counterparty risk. CRD article 80 and the implementing provisions of French law address a Covered Entity's management of residual risk. CRD article 81 and the implementing provisions of French law address a Covered Entity's management of concentration risk. CRD article 82 and the implementing provisions of French law address a Covered Entity's management of securitization risk. CRD article 83 and the implementing provisions of French law address a Covered Entity's management of market risk. CRD article 84 and the implementing provisions of French law address a Covered Entity's management of interest rate risk. CRD article 85 and the implementing provisions of French law address a Covered Entity's management of operational risk. CRD article 86 and the implementing provisions of French law address a Covered Entity's management of liquidity risk and funding risk. CRD article 87 and the implementing provisions of French law address a Covered Entity's management of risk from excessive leverage.
- MiFID article 16(4) and the implementing provisions of French law require a Covered Entity to take reasonable steps to ensure continuity and regularity in the performance of investment services and activities, including by employing appropriate and proportionate systems, resources and procedures. MiFID article 16(5) and the implementing provisions of French law require a Covered Entity to ensure that it manages the operational risk of

[137] *See* paras. (b)(3)(ii) of the Order. This condition promotes comparability with the Exchange Act rule requiring reports to the Commission regarding significant valuation disputes, while leveraging French and EU reporting provisions to avoid the need for Covered Entities to create additional reporting frameworks. When it proposed the condition to report valuation disputes, the Commission recognized that valuation inaccuracies may lead to uncollateralized credit exposure and the potential for loss in the event of default. *See* Exchange Act Release No. 84861 (Dec. 19, 2018), 84 FR 4614, 4621 (Feb. 15, 2019). It thus is important that the Commission be informed regarding valuation disputes affecting SBS Entities. The principal difference between the Exchange Act and French and EU valuation dispute reporting requirements concerns the timing of notices. Exchange Act rule 15Fi–3, 17 CFR 240.15Fi–3, requires SBS Entities to report promptly to the Commission valuation disputes in excess of $20 million that have been outstanding for three or five business days (depending on the counterparty type). EMIR RTS article 15(2) requires financial counterparties to report to the relevant competent authority at least monthly any disputes between counterparties in excess of €15 million and outstanding for at least 15 business days. The Commission is mindful that the French and EU provision does not provide for notice as quickly as rule 15Fi–3, but in the Commission's view on balance this difference would not be inconsistent with the conclusion that the two sets of requirements, taken as a whole, promote comparable regulatory outcomes.

[138] SIFMA Letter I at 4–5.

[139] *Id.* at 5.

[140] *Id.*

[141] SIFMA Letter II at Appendix A; FBF Letter II at 2.

[142] Better Markets Letter at 2.

[143] SIFMA Letter II at Appendix A.

relying on third parties for the performance of operational functions that are critical to the continuous and satisfactory provision of service to clients and performance of investment services and activities.

• CRR article 286 requires a Covered Entity to establish and maintain a counterparty credit risk management framework, including policies, processes and systems to ensure the identification, measurement, approval and internal reporting of counterparty credit risk and procedures for ensuring that those policies, processes and systems are complied with. CRR article 287 addresses the internal governance of risk control and collateral management functions for Covered Entities that use internal models to calculate capital requirements. CRR article 288 requires the Covered Entity to conduct regular, independent reviews of its counterparty credit risk management systems and any risk control and collateral management functions required by CRR article 287. CRR article 293 addresses internal governance of the Covered Entity's internal risk management systems and validation of risk models that the Covered Entity uses.

• EMIR Margin RTS article 2 requires counterparties to non-centrally cleared OTC derivative contracts to establish, apply and document risk management procedures for the exchange of collateral.

• MiFID Org Reg article 21 addresses a Covered Entity's systems, internal controls and arrangements for management of a variety of risk areas, including internal decision-making, allocation and proper discharge of responsibilities, compliance with decisions and internal procedures, employment of personnel able to discharge their responsibilities, internal reporting and communication of information, adequate and orderly recordkeeping, safeguarding information, business continuity, accounting policies and procedures, as well as regular evaluation of the adequacy and effectiveness of those systems, internal controls and arrangements. MiFID Org Reg article 22 addresses a Covered Entity's policies and procedures for detecting and minimizing risk of failure to comply with its obligations under EU provisions that implement MiFID, as well as the Covered Entity's independent compliance function that monitors and assesses the adequacy and effectiveness of those policies and procedures. MiFID Org Reg article 24 addresses a Covered Entity's internal audit function that evaluates the adequacy and effectiveness of the Covered Entity's systems, internal controls and arrangements.

Each of these requirements helps to produce regulatory outcomes comparable to Exchange Act requirements to establish robust and professional internal risk management systems adequate for managing the Covered Entity's day-to-day business. The comparability analysis requires consideration of Exchange Act requirements as a whole against analogous French and EU requirements as a whole, recognizing that U.S. and non-U.S. regimes may follow materially different approaches in terms of specificity and technical content. This ''as a whole'' approach—which the Commission is following in lieu of requiring requirement-by-requirement similarity—further means that the conditions to substituted compliance should encompass all French and EU requirements that establish comparability with the applicable regulatory outcome, and helps to avoid ambiguity in the application of substituted compliance. It would be inconsistent with the holistic approach to excise relevant requirements and leave only the residual French and EU provisions that most closely resemble the analogous Exchange Act requirements.[144] Accordingly, the Commission is retaining the references to these provisions. Retaining conditions of the Order necessary to help produce regulatory outcomes comparable to Exchange Act internal risk management requirements also should address another commenter's concern that any substituted compliance determination not weaken the risk control conditions in the proposed Order.[145]

The Commission is making three changes from the proposed Order for this portion of the Order. First, the Commission concurs with a commenter recommendation that the prerequisites to substituted compliance for internal risk management should not extend to the Covered Entity being subject to and complying with French Prudential Supervision and Risk Assessment Order article 7, which does not impose obligations on regulated entities.[146] Second, the Commission is incorporating, as part of the relevant conditions a Covered Entity using substituted compliance for internal risk management must be subject to and comply with, MFC L. 533–2, which is the French implementation of the internal risk management requirements set forth in the second paragraph of MiFID article 16(5).[147] Finally, the Commission is incorporating, as part of the relevant conditions, MiFID articles 16 and 23 and the related implementing provisions;[148] MiFID Org Reg articles 25 through 37, 72 through 76 and Annex IV; and CRD articles 88(1), 91(1) and (2), and (7) through (9), 92, 94, and 95 and the related implementing provisions.[149] These provisions address additional aspects of a Covered Entity's management of the risks posed by internal governance and organization, business operations, conflicts of interest with and between clients and senior staff remuneration policies.

In deciding to make a positive substituted compliance determination for French and EU internal risk management requirements, the Commission considers that the Order's condition requiring a Covered Entity to be subject to and comply with all of the French and EU internal risk management requirements listed in paragraph (b)(1) of the Order help to produce regulatory outcomes comparable to Exchange Act internal risk management requirements. The Commission recognizes that some of the French and EU requirements related to risk management follow a more granular approach than the high-level approach of Exchange Act internal risk management requirements, but these French and EU requirements, taken as a whole, are crafted to promote a Covered Entity's risk management. Within the requisite outcomes-oriented approach for analyzing comparability, the Commission concludes that a Covered Entity's failure to comply with any of those French and EU internal risk management requirements would be inconsistent with a Covered Entity's obligation under Exchange Act internal risk management requirements.[150] In

[144] The Commission further believes that those conditions to substituted compliance do not expand the scope of Exchange Act requirements because substituted compliance is an option available to non-U.S. person SBS Entities—not a mandate.

[145] *See* Better Markets Letter at 1–2.

[146] SIFMA Letter II at Appendix A.

[147] That cross-reference inadvertently was omitted from the proposed Order, but was incorporated within the proposed conditions related to internal supervision and compliance (*see* para. (d)(3) of the Order), and was cited by the French Authorities' Application as supporting comparability in connection with internal risk management system requirements (*see* French Authorities' Application at 68).

[148] MFC articles L. 533–10.II (1) through (3) and (6) through (9), L. 533–10.III, L. 533–24 and L. 533–24–1.

[149] MFC articles L. 511–51, L. 511–52.I, L. 511–53, L. 511–58, L. 511–59, L. 511–67 through L. 511–69, L. 511–71 through L. 511–85, L. 511–102, R. 511–18–2 and R. 511–16–3.

[150] One commenter recognized that the application addressed CRD requirements in connection with internal risk management

Continued

contrast to the assertion that such provisions ''go beyond the general requirements of Exchange Act section 15(j)(2),'' [151] the Commission concludes that compliance with the full set of French and EU internal risk management requirements listed in paragraph (b)(1) of the Order would promote comparable regulatory outcomes.

2. Trade Acknowledgement and Verification

Under the proposed Order, substituted compliance in connection with the Exchange Act rule 15Fi–2 trade acknowledgment and verification requirement would have been conditioned on firms having to comply with relevant confirmation requirements under MiFID and EMIR. Commenters expressed the view that the conditions should not incorporate MiFID confirmation provisions, based in part on the view that EMIR requirements standing alone would be sufficient to produce regulatory outcomes comparable to those under Exchange Act trade acknowledgement and verification requirements.[152] One commenter further stated that conditioning substituted compliance on SBS Entities having to comply with MiFID confirmation requirements in practice would undermine the availability of substituted compliance for SBS Entities that have branches in EU member states for which the Commission has not entered into an applicable substituted compliance memorandum of understanding.[153]

When the Commission reopened the comment period, it solicited additional comment on whether EMIR requirements were sufficient to produce comparable results, such that MiFID provisions may be removed as conditions to substituted compliance for trade acknowledgement and verification.[154] Some commenters generally supported the associated changes contemplated by the Commission in the Reopening Release.[155] On the other hand, one commenter stated its opinion that ''some industry participants may not be able to take advantage of substituted compliance under the SEC's proposed framework is not, in and of itself, a reason to change the framework''.[156] The same commenter stated that ''the French regulatory framework governing [trade acknowledgement] . . . does not satisfy the test for substituted compliance'' and that ''the Commission should certainly not weaken [the trade acknowledgment] conditions any further.'' [157]

The Commission agrees that, in and of itself, the fact that some may not be able to rely on the Order is not a sufficient reason to modify the Order. On the other hand, the Commission believes that the duplicative nature of the MiFID-related conditions and the EMIR-related conditions in light of the implementation issues warrants the removal of the MiFID-related conditions, and the Order has been modified accordingly.[158] In taking this step, the Commission has considered French and EU timely confirmation requirements. EMIR article 11 requires ''financial counterparties'' and ''non-financial counterparties'' to ensure appropriate procedures and arrangements are in place to achieve timely confirmation of the terms of an OTC derivative contract.[159] Similarly, EMIR RTS article 12 requires non-centrally cleared OTC derivative contracts between ''financial counterparties'' and ''non-financial counterparties'' to be confirmed.[160] These counterparty categories do not include entities organized outside the EU, such as U.S. persons.[161] Confirmation means the documentation of the agreement of the counterparties to all the terms of the OTC derivative contract.[162] The French and EU requirements as a whole thus require a Covered Entity [163] to provide a confirmation that serves as a trade acknowledgment, without regard to where its counterparty is organized, and also require the Covered Entity's counterparty, when it is a financial counterparty or non-financial counterparty, to provide a confirmation that serves as the trade verification, and the Commission considers these requirements to promote regulatory outcomes comparable to Exchange Act trade acknowledgment and verification requirements for those counterparties. The French and EU requirements in most instances do not require a Covered Entity's counterparty that is organized outside the EU to provide a French confirmation that serves as a trade verification,[164] though they do require the Covered Entity to confirm the transaction.[165] Confirmation is defined as documenting the agreement of the Covered Entity and its counterparties to all the terms of the OTC derivative contract.[166] To ensure that a Covered

requirements, but expressed the view that those discussions address comparability in connection with Exchange Act rule 18a–1(f), relating to risk management systems in connection with capital requirements. *See* SIFMA Letter I at 5 n.9. Regardless of applicants' rationale for citing those CRD requirements as supporting comparability, the Commission believes that the appropriate comparability analysis generally should seek to compare regulatory regimes taken as a whole, and that a Covered Entity's failure to comply with the applicable CRD risk management system requirements would not lead to a regulatory outcome consistent with that established by Exchange Act internal risk management requirements.

[151] SIFMA Letter II at Appendix A.

[152] *See* SIFMA Letter I at 5–6; FBF Letter I at 2; EBF Letter I (providing general support for SIFMA Letter I).

[153] *See* SIFMA Letter I at 2–4.

[154] *See* Reopening Release, 86 FR at 18343.

[155] *See* SIFMA Letter II at 6–7 (stating that the EMIR requirements ''are sufficient, standing alone, to reach comparable outcomes'' to the Exchange Act trade acknowledgement and verification (and trading relationship documentation) requirements, and that ''further requiring compliance with MiFID documentation requirements would substantially reduce the overall availability of substituted compliance in these areas because those MiFID requirements are not necessarily applicable on an entity-wide basis like the EMIR requirements are''); *see also* FBF Letter II at 2.

[156] Better Markets Letter at 2.

[157] *Id.*

[158] *See* para. (b)(2) of the Order.

[159] *See* EMIR article 11(1)(a).

[160] *See* EMIR RTS articles 12(1) and (2).

[161] *See* EMIR article 2(8) (definition of ''financial counterparty''); EMIR article 2(9) (definition of ''non-financial counterparty'').

[162] *See* EMIR RTS article 1(c).

[163] The Order defines a Covered Entity to include an investment firm or credit institution authorized by the ACPR. Investment firms and credit institutions are included in the definition of ''financial counterparty,'' so a Covered Entity is also a financial counterparty and thus is ''subject to'' EMIR article 11 and related provisions of EMIR RTS and EMIR Margin RTS for purposes of the Order.

[164] *See* EMIR article 2(8) (definition of ''financial counterparty'' limited to entities defined or authorized in a manner that in most instances is reserved for EU-established entities); EMIR article 2(9) (definition of ''non-financial counterparty'' limited to EU-established entities); EMIR articles 11(1)(a) and 11(12) (confirmation requirement applies to financial counterparties, non-financial counterparties and third-country entities that would be subject to the confirmation requirement if established in the EU and either the relevant contract has a direct, substantial and foreseeable effect in the EU or the obligation is necessary or appropriate to prevent the evasion of any provision of EMIR).

[165] As defined in paragraph (g)(1) of the Order, a Covered Entity must be an investment firm or credit institution authorized by the ACPR to provide investment services or perform investment activities in the French Republic. These investment firms and credit institutions are limited to French-established entities and do not include third-country firms. *See* MiFID article 4(57) (definition of ''third-country firm'' is a firm that would be a credit institution providing investment services or performing investment activities or an investment firm if its registered office or head office were located in the EU); MFC article L. 532–47 (same). Each of these investment firms and credit institutions also is among the entities that qualify as a ''financial counterparty.'' *See* EMIR article 2(8) (definition of ''financial counterparty'' includes credit institutions and investment firms).

[166] *See* EMIR RTS article 1(c). In other words, the Covered Entity would be subject to the relevant requirements under EMIR even if the counterparty is not authorized pursuant to EU law as anticipated by the EMIR article 2(8) ''financial counterparty'' definition or if the counterparty is not an ''undertaking'' (such as by virtue of being a natural

Entity using substituted compliance for trade acknowledgment and verification requirements will be required to document the agreement of the counterparties to all the terms of the relevant transaction, the Commission is issuing the Order with two new general conditions that will require the Covered Entity to treat its counterparty as a financial counterparty or non-financial counterparty when complying with French and EU trade acknowledgment and verification requirements and to ensure that the relevant security-based swap is either non-centrally cleared and subject to EMIR or cleared by a central counterparty that has been authorized or recognized to clear derivatives contracts by a relevant authority in the EU.[167]

Another commenter recommended removal of conditions requiring compliance with EMIR RTS article 12(4) because it does not relate to and goes beyond Exchange Act trade acknowledgment and verification requirements.[168] As part of the French and EU framework for trade acknowledgment and verification, EMIR RTS article 12(4) requires a Covered Entity to have the necessary procedures to report on a monthly basis to the competent authority the number of unconfirmed, non-centrally cleared OTC derivative transactions that have been outstanding for more than five business days. Though Exchange Act rule 15Fi–2 does not have a similar requirement to report unconfirmed trades, the Commission considers that EMIR RTS article 12(4)'s requirement to report unconfirmed trades to the competent authority is an inseparable part of the French and EU framework for trade acknowledgment and verification, as those reports support the framework's mandate to confirm transactions. Requiring a Covered Entity to be subject to and comply with EMIR RTS article 12(4) thus is consistent with a holistic approach for comparing regulatory outcomes that reflects the whole of a jurisdiction's relevant requirements. Accordingly, the Order retains as a condition to substituted compliance for trade acknowledgment and verification requirements the requirement that the Covered Entity be subject to and comply with the entirety of EMIR RTS article 12.

In summary, the Commission believes that French and EU requirements promote the goal of avoiding legal and operational risks by requiring definitive written records of transactions and procedures to avoid disagreements regarding the meaning of transaction terms, in a manner that is comparable to the purpose of Exchange Act rule 15Fi–2.[169] The Commission recognizes that the MiFID confirmation requirements, particularly MiFID Org Reg article 59, are more specific regarding relevant categories of information to be disclosed (in the context of a one-way requirement for firms to provide reports to their clients), but does not believe that those additional one-way confirmation provisions are necessary to achieve the policy goal of avoiding legal and operational risks. While the Commission recognizes the differences between French and EU requirements and Exchange Act trade acknowledgment and verification requirements, in the Commission's view those differences on balance would not preclude substituted compliance, particularly as requirement-by-requirement similarity is not needed for substituted compliance. The Commission is not persuaded by a commenter view that ''denying substituted compliance under the applicable circumstances seems perfectly reasonable,'' given the Commission's conclusion that the relevant EMIR-related conditions provide regulatory outcomes that are comparable to those associated with the Exchange Act requirement, and the regulatory efficiency benefits associated with substituted compliance.[170] That commenter's request for a ''robust, evidence-based analysis'' has been met here in the context of the requisite holistic analysis,[171] and the commenter's suggestion that there is a need for analysis regarding protection of the American financial system has been addressed above.[172]

3. Portfolio Reconciliation and Dispute Reporting

In the French Substituted Compliance Notice and Proposed Order, the Commission proposed to make a positive substituted compliance determination conditioned on the Covered Entity being subject to and complying with specific French portfolio reconciliation and dispute reporting requirements.[173] One commenter expressed general support for the proposed approach toward substituted compliance for the risk control provisions.[174] Another commenter stated that, if the Commission makes a positive substituted compliance determination, it must at a minimum ensure that it does ''not weaken [the] conditions any further.''[175] The Commission continues to believe that French portfolio reconciliation and dispute reporting requirements promote regulatory outcomes comparable to Exchange Act requirements, by subjecting Covered Entities to risk mitigation practices that are appropriate to the risks associated with their security-based swap businesses, and is making a positive substituted compliance determination

person) or is not established in the EU (by virtue of being a U.S. person or otherwise being established in some non-EU jurisdiction), as anticipated by the EMIR article 2(9) ''non-financial counterparty'' definition. This approach appears to be consistent with EU guidance. *See* European Securities and Markets Authority, ''Questions and Answers: Implementation of the Regulation (EU) No 648/2012 on OTC derivatives, central counterparties and trade repositories (EMIR)'' (*https://www.esma.europa.eu/sites/default/files/library/esma70-1861941480-52_qa_on_emir_implementation.pdf*) answer 5(a) (stating that compliance with the EMIR confirmation requirement necessitates that the counterparties must reach a legally binding agreement to all terms of the OTC derivative contract, and that the EMIR RTS ''implies'' that both parties must comply and agree in advance to a specific process to do so); answer 12(b) (stating that where an EU counterparty transacts with a third-country entity, the EU counterparty generally must ensure that the EMIR requirements for portfolio reconciliation, dispute resolution, timely confirmation and portfolio compression are met for the relevant portfolio and/or transactions even though the third country entity would not itself be subject to EMIR).

[167] *See* paras. (a)(5) and (a)(6) of the Order; *see also* part III.B, *supra.* Commenters supported those additions. *See* FBF Letter II at 2 (stating that ''[t]he FBF is generally welcoming of the new general EMIR conditions that are introduced as a corollary to the above changes. As applied in the context of trading relationship documentation, trade acknowledgment and verification, they largely convey the manner in which EMIR has been interpreted.''). *See also* SIFMA Letter II at 6 (stating that ''we agree with the Commission that the cited provisions of EMIR are comparable to the Exchange Act trade acknowledgment and verification and trading relationship documentation requirements.'').

[168] *See* SIFMA Letter II at Appendix A (stating that the requirements of the rule, which relate to the obligation of financial counterparties to report, on a monthly basis, the number of unconfirmed OTC derivative transactions that have been outstanding for more than five business days, ''do not correspond to and go beyond the general requirements of'' rule 15Fi–2).

[169] The two new EMIR-related general conditions addressed above should further help ensure that the EMIR confirmation provisions comprehensively apply to relevant non-cleared transactions of SBS Entities.

[170] Better Markets Letter at 6.

[171] *See* Better Markets Letter at 6 (alluding to the need for a ''robust, evidence-based analysis''). As discussed above (*see* part II.D.2, *supra*), the Commission believes that the present approach toward comparability analyses—which are based on a close reading of relevant foreign requirements and careful consideration of regulatory outcomes—appropriately reflects the holistic comparability approach and the rejection of requirement-by-requirement similarity.

[172] *See* Better Markets Letter at 6 (stating that the Commission must provide analysis that the change would protect the American financial system). *See also* discussion in part II.D.2 *supra*).

[173] French Substituted Compliance Notice and Proposed Order, 85 FR at 85740.

[174] *See* SIFMA Letter II at 6.

[175] *See* Better Markets Letter at 2.

for portfolio reconciliation and dispute reporting requirements consistent with the proposed Order.[176] Substituted compliance in connection with the dispute reporting requirements is conditioned in part on the Covered Entities providing the Commission with reports regarding disputes between counterparties on the same basis as the entities provide those reports to competent authorities pursuant to EU law, to allow the Commission to obtain notice regarding key information in a manner that makes use of existing obligations under EU law.[177]

4. Portfolio Compression

In the French Substituted Compliance Notice and Proposed Order, the Commission proposed to make a positive substituted compliance determination conditioned on the Covered Entity being subject to and complying with specific French portfolio compression requirements.[178] One commenter expressed general support for the proposed approach toward substituted compliance for the risk control provisions.[179] Another commenter stated that, if the Commission makes a positive substituted compliance determination, it must at a minimum ensure that it does ''not weaken [the] conditions any further.'' [180] The Commission continues to believe that French portfolio compression requirements promote regulatory outcomes comparable to Exchange Act requirements, by subjecting Covered Entities to risk mitigation practices that are appropriate to the risks associated with their security-based swap businesses, and is making a positive substituted compliance determination for portfolio compression requirements consistent with the proposed Order.[181]

5. Trading Relationship Documentation

Under the proposed Order, substituted compliance in connection with the Exchange Act rule 15Fi–5 trading relationship documentation requirement would have been conditioned on Covered Entities being subject to and complying with MiFID and EMIR provisions that address records regarding counterparty relationships and entities.[182] Substituted compliance under the proposed Order would not extend to rule 15Fi–5(b)(5) insolvency-related disclosures when the counterparty is a U.S. person.[183]

Consistent with the comments addressed above with respect to trade acknowledgement and verification, some commenters requested that substituted compliance for trading relationship documentation not incorporate conditions requiring compliance with MiFID documentation requirements.[184] Those commenters expressed the view that compliance with MiFID requirements would not be feasible for Covered Entities that have branches in third countries, and that the EMIR risk management provisions connected to the exchange of collateral are sufficient to produce regulatory outcomes comparable to those under the Exchange Act trading relationship documentation rule.[185]

As noted above, the Commission reopened the comment period and solicited additional comment on whether EMIR requirements standing alone could produce comparable results such that certain MiFID provisions may be removed as prerequisites to substituted compliance.[186] Some commenters generally supported the associated changes contemplated by the Commission in the Reopening Release [187] (including the addition of two new EMIR-related general conditions addressed above),[188] while one commenter opposed removal of the MiFID conditions.[189]

The Commission concludes that the implementation issues raised by commenters warrant removal of the MiFID-related condition, and that compliance with EMIR-based risk management requirements are sufficient to produce risk-mitigating outcomes that are comparable to those associated with the Exchange Act rule. The Order accordingly has been modified from the proposed Order to remove conditions requiring compliance with MiFID trading relationship documentation requirements, including corollary conditions related to the application of the MiFID to ''eligible counterparties.'' [190] In reaching this conclusion, the Commission highlights the special importance of EMIR Margin RTS article 2, which addresses risk management procedures related to the exchange of collateral, including procedures related to the terms of all necessary agreements to be entered into by counterparties (*e.g.,* payment obligations, netting conditions, events of default, calculation methods, transfers of rights and obligations upon termination, and governing law). Those obligations are denoted as being connected to collateral exchange obligations, and the Commission believes that they are necessary to help produce a regulatory outcome that mitigates risk in a manner that is comparable to the outcome associated with the Exchange Act trading relationship documentation rule. To bridge any gap left by EMIR Margin RTS article 2, the Commission is also requiring compliance with EMIR article 11(1)(a) and EMIR RTS article 12, which require the Covered Entity to confirm the transaction, with confirmation defined as documentation of the agreement of the counterparties to all the terms of the OTC derivative contract.[191]

To ensure that a Covered Entity using substituted compliance for trading relationship documentation requirements will be required to document the agreement of the counterparties to all the terms of the relevant transaction, the Commission is issuing the Order with two new general conditions that will require the Covered Entity to treat its counterparty as a financial counterparty or non-financial counterparty when complying French and EU trading relationship documentation requirements and to ensure that the relevant security-based swap is either non-centrally cleared and subject to EMIR or cleared by a central counterparty that has been authorized or recognized to clear derivatives contracts

[176] *See* para. (b)(3) of the Order.

[177] *See* para. (b)(3)(ii) of the Order. The Commission recognizes the differences between the two sets of requirements—under which Exchange Act rule 15Fi–3 requires SBS Entities to report valuation disputes in excess of $20 million that have been outstanding for three or five business days (depending on counterparty types), while EMIR RTS art. 15(2) requires firms to report disputes between counterparties in excess of €15 million and outstanding for at least 15 business days. In the Commission's view, the two requirements produce comparable regulatory outcomes notwithstanding those differences.

[178] French Substituted Compliance Notice and Proposed Order, 85 FR at 85740.

[179] *See* SIFMA Letter II at 6.

[180] *See* Better Markets Letter at 2.

[181] *See* para. (b)(4) of the Order.

[182] *See* para. (b)(5) of the proposed Order.

[183] French Substituted Compliance Notice and Proposed Order, 85 FR at 85725.

[184] *See* SIFMA Letter I at 6.

[185] *See* SIFMA Letter I at 3–4.

[186] *See* part III.B, *supra.*

[187] *See* SIFMA Letter II at 6; *see also* FBF Letter II at 2.

[188] *See* part III.B.2.d, *supra.*

[189] *See* Better Markets Letter at 6–7.

[190] *See* para. (b)(5) of the Order. Consistent with the proposed Order, substituted compliance in connection with trading relationship documentation requirements does not extend to Exchange Act rule 15Fi–5(b)(5) provisions related to disclosures regarding legal and bankruptcy status when the counterparty is a U.S. person.

[191] One commenter suggested including EMIR article 11(1)(a) and EMIR RTS article 12(1) through (3). The Commission agrees that these provisions are necessary to a finding of comparability. *See* SIFMA Letter II at Appendix A. As discussed in part IV.B.2 the Commission believes that EMIR RTS article 12(4) is relevant to its holistic, outcomes-oriented approach.

by a relevant authority in the EU.[192] The Commission agrees with a commenter that the other proposed conditions to substituted compliance for trading relationship documentation should be retained.[193]

V. Substituted Compliance for Capital and Margin Requirements

A. Proposed Approach

The French Authorities' Application in part requests substituted compliance in connection with requirements under the Exchange Act relating to:

• *Capital*—Capital requirements pursuant to Exchange Act section 15F(e) and Exchange Act rule 18a–1 and its appendices (collectively ''Exchange Act rule 18a–1'') applicable to certain SBS Entities.[194] Exchange Act rule 18a–1 helps to ensure the SBS Entity maintains at all times sufficient liquid assets to promptly satisfy its liabilities, and to provide a cushion of liquid assets in excess of liabilities to cover potential market, credit, and other risks. The rule's net liquid assets test standard protects customers and counterparties and mitigates the consequences of an SBS Entity's failure by promoting the ability of the firm to absorb financial shocks and, if necessary, to self-liquidate in an orderly manner.[195] As part of the capital requirements, security-based swap dealers without a prudential regulator also must comply with the internal risk management control requirements of Exchange Act rule 15c3–4 with respect to certain activities.[196]

• *Margin*—Margin requirements pursuant to Exchange Act section 15F(e) and Exchange Act rule 18a–3 for non-prudentially regulated SBS Entities.[197] The margin requirements are designed to protect SBS Entities from the consequences of a counterparty's default.[198]

Taken as a whole, these capital and margin requirements help to promote market stability by mandating that SBS Entities follow practices to manage the market, credit, liquidity, solvency, counterparty, and operational risks associated with their security-based swap businesses.

In proposing to provide conditional substituted compliance in connection with this part of the French Authorities' Application, the Commission's preliminary view was that relevant French and EU requirements would produce regulatory outcomes that are comparable to those associated with the above capital and margin requirements, by subjecting Covered Entities to financial responsibility requirements that are appropriate to the risks associated with their security-based swap businesses.[199] Substituted compliance accordingly would be conditioned on Covered Entities being subject to the French and EU provisions that, in the aggregate, establish a framework that produces outcomes comparable to those associated with the capital and margin requirements under the Exchange Act.[200]

However, the Commission also sought comment on whether substituted compliance with respect to Exchange Act capital requirements should be subject to additional conditions.[201] In particular, the Commission sought comment on the following potential conditions:

• A condition that would require a Covered Entity to maintain a minimum amount of liquid assets, such as a minimum ratio of liquid assets to illiquid assets (*e.g.,* a ratio of liquid assets to illiquid assets of 80% to 20%, 70% to 30%, 60% to 40%). With respect to such a ratio, the Commission also requested comment on whether liquid and illiquid assets should be defined using the concept of assets that are allowable or not allowable as capital under Exchange Act rule 18a–1.

• A condition that would require a Covered Entity to be subject to a specific liquidity requirement, such as a requirement to maintain a pool of highly liquid assets to cover cash outflows during a 30-day period of stress.

• A condition that a Covered Entity must maintain equity capital or Tier 1 capital at least equal to the minimum fixed-dollar capital requirements under Exchange Act rule 18a–1 (*e.g.,* equity capital or Tier 1 capital of at least $20 million).

Additionally, in the Reopening Release, the Commission again sought comment on whether substituted compliance with respect to Exchange Act capital requirements should be subject to additional conditions.[202] The Commission explained that the capital standard of Exchange Act rule 18a–1 is a net liquid assets test. Under this standard, an SBS Entity will have more than a dollar of highly liquid assets for each dollar of unsubordinated liabilities. Covered Entities, however, are subject to capital requirements applicable to prudentially regulated entities based on the international capital standard for banks (the ''Basel capital standard'').[203] The Basel capital standard counts as capital assets that Exchange Act rule 18a–1 would exclude (*e.g.,* loans and most other types of uncollateralized receivables, furniture and fixtures, real estate, and initial margin posted to counterparties). Consequently, because of the ability to include illiquid assets and margin posted away as capital, Covered Entities subject to the Basel capital standard may have less balance sheet liquidity than SBS Entities subject to Exchange Act rule 18a–1. For this reason, the Commission sought comment on the following potential conditions to

[192] *See* paras. (a)(5) and (a)(6) of the Order; *see also* part III.B, *supra.* Commenters supported those additions. *See* FBF Letter II at 2 (stating that ''[t]he FBF is generally welcoming of the new general EMIR conditions that are introduced as a corollary to the above changes. As applied in the context of trading relationship documentation, trade acknowledgment and verification, they largely convey the manner in which EMIR has been interpreted.''). *See also* SIFMA Letter II at 6 (stating that ''we agree with the Commission that the cited provisions of EMIR are comparable to the Exchange Act trade acknowledgment and verification and trading relationship documentation requirements.'').

[193] *See* Better Markets Letter at 1–2.

[194] 17 CFR 240.18a–1 through 18a–1d. Exchange Act rule 18a–1 applies to security-based swap dealers that: (1) Do not have a prudential regulator; and (2) are either (a) not dually registered with the Commission as a broker-dealer; or (b) are dually registered with the Commission as a special purpose broker-dealer known as an OTC derivatives dealer. Security-based swap dealers that are dually registered with the Commission as a full-service broker-dealer are subject to the capital requirements of Exchange Act rule 15c3–1 (17 CFR 240.15c3–1) for which substituted compliance is not available. *See* Exchange Act rule 3a71–6(d)(4)(i) (making substituted compliance available only with respect to the capital requirements of Exchange Act section 15F(e) and Exchange Act rule 18a–1).

[195] *See* Capital and Margin Adopting Release, 84 FR at 43879. The capital standard of Exchange Act rule 18a–1 is based on the net liquid assets test of Exchange Act rule 15c3–1 applicable to broker-dealers. *Id.* The net liquid assets test seeks to promote liquidity by requiring that a firm maintain sufficient liquid assets to meet all liabilities, including obligations to customers, counterparties, and other creditors, and, in the event a firm fails financially, to have adequate additional resources to wind-down its business in an orderly manner without the need for a formal proceeding. *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85726. *See* French Authorities' Application Annex 1 category 1 capital portion at 1–24.

[196] *See* 17 CFR 240.15c3–4 and 18a–1(f).

[197] 17 CFR 240.18a–3.

[198] *See* Capital and Margin Adopting Release, 84 FR at 43947, 43949 (''Obtaining collateral is one of the ways OTC derivatives dealers manage their credit risk exposure to OTC derivatives counterparties. Prior to the financial crisis, in certain circumstances, counterparties were able to enter into OTC derivatives transactions without having to deliver collateral. When 'trigger events' occurred during the financial crisis, those counterparties faced significant liquidity strains when they were required to deliver collateral'').

[199] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85726.

[200] *Id.* at 85726 n.49.

[201] *Id.* at 85736–37.

[202] *See* Reopening Release, 86 FR at 18343–47.

[203] *See, e.g.,* Basel Committee on Banking Supervision (''BCBS''), The Basel Framework, available at: *https://www.bis.org/basel_framework/.*

applying substituted compliance to Exchange Act rule 18a–1:

- A condition that would require a Covered Entity to maintain an amount of assets that are allowable under Exchange Act rule 18a–1, after applying applicable haircuts under the Basel capital standard, that equals or exceeds the Covered Entity's current liabilities coming due in the next 365 days.
- A condition that would require a Covered Entity to make a quarterly record listing: (1) The assets maintained pursuant to the above condition, their value, and the amount of their applicable haircuts; and (2) the aggregate amount of the liabilities coming due in the next 365 days.
- A condition that would require a Covered Entity to maintains at least $100 million of equity capital composed of highly liquid assets, as defined in the Basel capital standard.
- A condition that would require a Covered Entity to include its most recent statement of financial condition (*i.e.,* balance sheet) filed with its local supervisor whether audited or unaudited with its written notice to the Commission of its intent to rely on substituted compliance.

B. Commenter Views and Final Provisions

1. Capital

Consistent with the proposed Order, the first capital condition requires the covered entity to be subject to and comply with certain identified French and EU capital requirements.[204] As discussed at the end of this section, the Commission made some modifications to the French and EU laws and regulations cited in this condition.[205] For the reasons discussed below, there are two additional conditions to applying substituted compliance with respect to Exchange Act rule 18a–1.

For the reasons discussed above in part III.B.2.e of this release, the first additional capital condition is that the Covered Entity applies substituted compliance with respect to Exchange Act rules 18a–5(a)(9) (a record making requirement), 18a–6(b)(1)(x) (a record preservation requirement), and 18a–8(a)(1)(i), (a)(1)(ii), (b)(1), (b)(2), and (b)(4) (notification requirements).[206] These recordkeeping and notification requirements are directly linked to the capital requirements of Exchange Act rule 18a–1. The UK Proposed Order conditioned substituted compliance with respect to these recordkeeping and notification requirements on the Covered Entity applying substituted compliance with respect to Exchange Act rule 18a–1.[207] This additional capital condition is designed to provide clarity as to the Covered Entity's obligations under these recordkeeping and notification requirements when applying substituted compliance with respect to Exchange Act rule 18a–1 pursuant this Order.

The second additional capital condition builds on and modifies the proposed capital condition that was the subject of the Commission's questions in the Reopening Release and that was designed to address potential different regulatory outcomes between Exchange Act rule 18a–1 and the French and EU capital requirements. In particular, the Commission asked questions about a four pronged condition with respect to applying substituted compliance to the capital requirements of Exchange Act rule 18a–1.[208] The first prong would require a Covered Entity to maintain an amount of assets that are allowable under Exchange Act rule 18a–1, after applying applicable haircuts under the Basel capital standard, that equals or exceeds the Covered Entity's current liabilities coming due in the next 365 days.[209] The second prong was linked to the first prong as it would require that a Covered Entity make a quarterly record listing: (1) The assets maintained pursuant to the first condition, their value, and the amount of their applicable haircuts; and (2) the aggregate amount of the liabilities coming due in the next 365 days. The third prong would require the Covered Entity to maintain at least $100 million of equity capital composed of highly liquid assets as defined in the Basel capital standard. The fourth prong would require the Covered Entity to include its most recently filed statement of financial condition whether audited or unaudited with its initial notice to the Commission of its intent to rely on substituted compliance.

One commenter recommended that the Commission consider denying substituted compliance for capital requirements on the basis that France's capital requirements do not produce comparable regulatory outcomes.[210] This commenter stated that ''granting substituted compliance with multiple conditions intended to mimic the Commission's capital requirements would seem to undermine the entire point of substituted compliance in the first place; namely, protecting the stability of the U.S. financial system by allowing substituted compliance *only when* foreign regimes are comparable.'' [211]

In describing the differences in the capital frameworks between the net liquid assets test and the Basel capital standard, this commenter highlighted the treatment of initial margin posted to a counterparty.[212] Specifically, the commenter stated that in France initial margin posted to a counterparty counts as capital for that entity, while in the U.S. initial margin only counts as capital if the security-based swap dealer has a special loan agreement with an affiliate. The commenter stated that the U.S. requirement is intended to mitigate counterparty credit risk with respect to the return of the initial margin. The commenter argued that the result is that, not only are the French requirements different from the Commission's in both form and substance, but the regulatory outcome is not comparable.

This commenter also stated that if a positive substituted compliance determination is made regarding capital, the Commission should not weaken the potential additional capital condition discussed in the Reopening Release in response to industry commenters, because these market participants are primarily concerned with reducing their own operational costs, without any regard to the systemic risk that would doing so would pose.[213] This commenter also stated that any determination to find Frances's capital requirements comparable to and as comprehensive as the Commission's capital framework without conditions at least as strong as proposed would not only contravene the Commission's own conception of substituted compliance ''but expose the U.S. financial system to very risks Dodd-Frank instructed the SEC to contain.'' [214]

Another commenter supported the potential capital condition.[215] This commenter stated that the Commission should require Covered Entities to

[204] *See* para. (c)(1)(i) of the order. *See also* French Substituted Compliance Notice and Proposed Order, 85 FR at 85726.

[205] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85726, n.49.

[206] *See* para. (c)(1)(ii) of the Order.

[207] *See* UK Substituted Compliance Notice and Proposed Order, 86 FR at 18395–403, 18416–17, 19419. The Commission sought comment in the Reopening Release on whether this approach should be taken in the final Order. *See* Reopening Release, 86 FR at 18348.

[208] *See id.* at 18387–89 (discussing the additional conditions).

[209] As used in this part V.B.1 of the release, the term ''Covered Entity'' refers to a security-based swap dealer located in the UK that does not have a prudential regulator.

[210] Better Markets Letter at 7–8.

[211] Better Markets Letter at 8 (emphasis in the original).

[212] Better Markets Letter at 7–8.

[213] Better Markets Letter at 7–8.

[214] Better Markets Letter at 7–8.

[215] AFREF Letter at 1.

comply with the net liquid assets test under Exchange Act rule 18a–1, rather than the Basel capital standards.[216] The commenter stated that the net liquid assets test ''appropriately limits uncollateralized lending, fixed assets, and other illiquid assets such as real estate which have been proven repeatedly to be unreliable forms of capital but are currently counted'' as allowable capital under the Basel capital standard.[217] This commenter also agreed with the Commission that ''the initial margin that is posted is not available for other purposes and therefore, under the Basel standard, could swiftly result in less balance sheet liquidity than the standards under the Exchange Act's Rule 18a–1.'' [218]

A commenter supported the Commission's proposed Order to grant substituted compliance in connection with the Exchange Act capital requirements.[219] This commenter, however, opposed additional capital conditions.[220] The commenter reiterated this opposition with respect to the potential four pronged capital condition for which the Commission sought comment in the Reopening Release.[221] The commenter stated that the potential capital condition was unnecessary, unduly rushed, and highly likely to be costly and disruptive to market participants and inconsistent with the Commission's substituted compliance framework.[222] More specifically, this commenter stated that the potential capital conditions was unnecessary because Covered Entities transact predominantly in securities and derivatives, do not extensively engage in unsecured lending or other activities more typical of banks, and are already subject to extensive liquidity requirements.[223] The commenter also expressed concern that the potential capital condition was inconsistent with the Commission's substituted compliance framework in that it was duplicative of and would contradict the liquidity requirements established by French and EU authorities.[224] This commenter stated that the imposition of the potential capital condition would effectively substitute the Commission's judgment for that of the French and EU authorities in terms of the best way to address liquidity risk, and may lead other regulators to refuse to extend deference to the Commission's regulatory determinations.[225]

With respect to the using the concept of ''allowable'' and ''nonallowable'' assets under Exchange Act rule 18a–1, the commenter stated that the first and second prongs of the potential capital condition do not define these terms and there is no analogous concept in the capital framework applicable in France.[226] The commenter stated this would require firms to re-categorize every asset on their balance sheets, which would not be feasible in the near term.[227] Further, this commented asked the Commission to clarify what it means by ''haircuts'' with respect to the first and second prongs, since the Basel capital standard does not apply ''haircuts'' to assets, but instead applies a risk-weighted approach.[228]

This commenter also stated that the third prong of the potential additional capital condition requiring ''at least $100 million of equity capital composed of 'highly liquid assets' as defined in the Basel capital standard,'' includes concepts that require clarification.[229] For example, this commenter stated that is unclear how a firm would calculate the amount of its ''equity capital'' that is ''composed of highly liquid assets,'' since ''equity'' generally refers to a firm's paid-in capital, retained earnings and other items on the liabilities/shareholders' equity side of the balance sheet.[230] Finally, this commenter asserted that because it is approximately three months until the August 6th counting date, and firms may encounter significant operational challenges to meet the potential or revised capital condition, the potential condition may cause firms to exit the U.S. security-based swap market, or hope that the conditions are modified and delayed in a manner that will make it feasible to satisfy them.[231]

Overall, this commenter stated that the Commission should take a more incremental and deliberative approach to additional capital conditions, and specifically recommended that the Commission: (1) Delete the first prong of the capital condition; (2) replace the second prong with a requirement that a nonbank Covered Entity provide the same reports concerning liquidity metrics that the Covered Entity provides to the French and EU authorities; (3) modify the third prong to require a nonbank Covered Entity to maintain at least $100 million of high quality liquid assets, as defined in the Basel capital standard; and (4) issue an order on October 6, 2024, determining whether to maintain, delete, modify or supplement the condition, based on consideration of the liquidity of nonbank Covered Entities, and after publishing a notice of any such changes for at least 90 days of public comment.[232]

The Commission agrees with the commenters who point out the differences between the capital standard of Exchange Act rule 18a–1 (*i.e.,* the net liquid assets test) and the Basel capital standard applicable to Covered Entities, and who therefore believe that—at a minimum—additional capital conditions are necessary to achieve comparable regulatory outcomes.[233] As the Commission explained when seeking comment on the potential additional capital condition, the net liquid assets test is designed to promote liquidity.[234] In particular, Exchange Act rule 18a–1 allows an SBS Entity to engage in activities that are part of conducting a securities business (*e.g.,* taking securities into inventory) but in a manner that places the firm in the position of holding at all times more than one dollar of highly liquid assets for each dollar of unsubordinated liabilities (*e.g.,* money owed to customers, counterparties, and creditors).[235] For example, Exchange

[216] *See id.* (''We support the Commission's proposal to require foreign security-based swap dealers and participants (''Covered Entities'') to abide by capital and initial margin requirements that reflect Exchange Act rule 18a–1 standards appropriate for broker-dealers, as opposed to Basel capital requirements for banks that permit illiquid assets to count toward capital minimums.'').

[217] *Id.*

[218] *Id.* at 2.

[219] SIFMA Letter I at 10. *See also* FBF Letter I at 4; EBF Letter I at 1 (generally supporting SIFMA Letter I).

[220] SIFMA Letter I at 11–13. *See also* FBF Letter I at 4.

[221] SIFMA Letter II at 7–17. *See also* EBF Letter II at 1 (''The EBF further shares SIFMA's serious concerns that the potential conditions to substituted compliance with capital requirements described in the Release would create brand new, far-ranging capital and liquidity requirements that could not be established prior to the compliance date.'') and FBF II Letter at 3–4 (''Last but certainly not least, the FBF shares SIFMA's serious concerns that the potential conditions to substituted compliance with capital requirements described in the Release would result in brand new, far-ranging capital and liquidity requirements that could not be established in time for registration, and would essentially force an exit of the relevant entity category from the U.S. SBS market prior to the de minimis counting date.'')

[222] SIFMA Letter II at 7–17.

[223] SIFMA Letter II at 8.

[224] SIFMA Letter II at 12–14.

[225] SIFMA Letter II at 13.

[226] SIFMA Letter II at 14.

[227] SIFMA Letter II at 14.

[228] SIFMA Letter II at 14.

[229] SIFMA Letter II at 15.

[230] SIFMA Letter II at 15.

[231] SIFMA Letter II at 15–16.

[232] SIFMA Letter II at 16–17.

[233] *See* AFREF Letter at 1–2; Better Markets Letter at 7–8.

[234] *See* Reopening Release, 86 FR at 18343–45 (explaining the differences between Exchange Act rule 18a–1 and the Basel capital standard).

[235] *See, e.g.,* Exchange Act Release No. 8024 (Jan. 18, 1967), 32 FR 856 (Jan. 25, 1967) (''Rule 15c3–1 (17 CFR 240.15c3–1) was adopted to provide safeguards for public investors by setting standards of financial responsibility to be met by brokers and

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Act rule 18a–1 allows securities positions to count as allowable net capital, subject to standardized or internal model-based haircuts. The rule, however, does not permit most unsecured receivables to count as allowable net capital. This aspect of the rule limits the ability of SBS Entities to engage in activities, such as uncollateralized lending, that generate unsecured receivables. The rule also does not permit fixed assets or other illiquid assets to count as allowable net capital, which creates disincentives for SBS Entities to own real estate and other fixed assets that cannot be readily converted into cash. For these reasons, Exchange Act rule 18a–1 incentivizes SBS Entities to confine their business activities and devote capital to security-based swap activities.

The net liquid assets test is imposed through how an SBS Entity is required to compute net capital pursuant to Exchange Act rule 18a–1. The first step is to compute the SBS Entity's net worth under U.S. generally accepted accounting principles (''GAAP''). Next, the SBS Entity must make certain adjustments to its net worth to calculate net capital, such as deducting illiquid assets and taking other capital charges and adding qualifying subordinated loans.[236] The amount remaining after these deductions is defined as ''tentative net capital.'' Exchange Act rule 18a–1 prescribes a minimum tentative net capital requirement of $100 million for SBS Entities approved to use models to calculate net capital. An SBS Entity that is meeting its minimum tentative net capital requirement will be in the position where each dollar of unsubordinated liabilities is matched by more than a dollar of highly liquid assets.[237] The final step in computing net capital is to take prescribed percentage deductions (standardized haircuts) or model-based deductions from the mark-to-market value of the SBS Entity's proprietary positions (*e.g.,* securities, money market instruments, and commodities) that are included in its tentative net capital. The amount remaining is the firm's net capital, which must exceed the greater of $20 million or a ratio amount.

In comparison, Covered Entities in France are subject to the Basel capital standard. The Basel capital standard counts as capital assets that Exchange Act rule 18a–1 would exclude (*e.g.,* loans and most other types of uncollateralized receivables, furniture and fixtures, real estate). The Basel capital standard accommodates the business of banking: Making loans (including extending unsecured credit) and taking deposits. While the Covered Entities that will apply substituted compliance with respect to Exchange Act rule 18a–1 will not be banks, the Basel capital standard allows them to count illiquid assets such as real estate and fixtures as capital. It also allows them to treat unsecured receivables related to activities beyond dealing in security-based swaps as capital notwithstanding the illiquidity of these assets.

Further, one critical example of the difference between the requirements of Exchange Act rule 18a–1 and the Basel capital standard relates to the treatment of initial margin with respect to security-based swaps and swaps. Under the French margin requirements, Covered Entities will be required to post initial margin to counterparties unless an exception applies.[238] Under Exchange Act rule 18a–1, an SBS Entity cannot count as capital the amount of initial margin posted to a counterparty unless it enters into a special loan agreement with an affiliate.[239] The special loan agreement requires the affiliate to fund the initial margin amount and the agreement must be structured so that the affiliate—rather than the SBS Entity—bears the risk that the counterparty may default on the obligation to return the initial margin. The reason for this restrictive approach to initial margin posted away is that it ''would not be available [to the SBS Entity] for other purposes, and, therefore, the firm's liquidity would be reduced.''[240] Under the Basel capital standard, a Covered Entity can count initial margin posted away as capital without the need to enter into a special loan arrangement with an affiliate. Consequently, because of the ability to include illiquid assets and margin posted away as capital, Covered Entities subject to the Basel capital standard may have less balance sheet liquidity than SBS Entities subject to Exchange Act rule 18a–1.

For these reasons, the Commission disagrees with the commenter who stated that additional capital conditions were unnecessary and inconsistent with the Commission's substituted compliance framework.[241] As discussed above, there are key differences between the net liquid assets test of Exchange Act rule 18a–1 and the Basel capital standard applicable to Covered Entities. Those differences in terms of the types of assets that count as regulatory capital and how regulatory capital is calculated lead to different regulatory outcomes.[242] In particular, the net liquid assets test produces a regulatory outcome in which the SBS Entity has more than one dollar of highly liquid assets for each dollar of unsubordinated liabilities.[243] The Basel capital standard—while having measures designed to promote

dealers. The basic concept of the rule is liquidity; its object being to require a broker-dealer to have at all times sufficient liquid assets to cover his current indebtedness.'') (footnotes omitted); Exchange Act Release No. 10209 (June 8, 1973), 38 FR 16774 (June 26, 1973) (Commission release of a letter from the Division of Market Regulation) (''The purpose of the net capital rule is to require a broker or dealer to have at all times sufficient liquid assets to cover its current indebtedness. The need for liquidity has long been recognized as vital to the public interest and for the protection of investors and is predicated on the belief that accounts are not opened and maintained with broker-dealers in anticipation of relying upon suit, judgment and execution to collect claims but rather on a reasonable demand one can liquidate his cash or securities positions.''); Exchange Act Release No. 15426 (Dec. 21, 1978), 44 FR 1754 (Jan. 8, 1979) (''The rule requires brokers or dealers to have sufficient cash or liquid assets to protect the cash or securities positions carried in their customers' accounts. The thrust of the rule is to insure that a broker or dealer has sufficient liquid assets to cover current indebtedness.''); Exchange Act Release No. 26402 (Dec. 28, 1988), 54 FR 315 (Jan. 5, 1989) (''The rule's design is that broker-dealers maintain liquid assets in sufficient amounts to enable them to satisfy promptly their liabilities. The rule accomplishes this by requiring broker-dealers to maintain liquid assets in excess of their liabilities to protect against potential market and credit risks.'') (footnote omitted).

[236] *See* 17 CFR 240.15c3–1(c)(2).

[237] The highly liquid assets under Exchange Act rule 18a–1 are otherwise known as ''allowable assets'' because they are not deducted when computing net capital. *See* Books and Records Adopting Release, 84 FR at 68673–74, 68677–80 (the sections of the amended Part II of the FOCUS Report setting forth the assets side of the balance sheet and the net capital computation). Illiquid assets otherwise known as ''non-allowable assets'' are deducted when computing net capital. *Id.* Allowable assets include cash, certain unsecured receivables from broker-dealers and clearing organizations, reverse repurchase agreements, securities borrowed, fully secured customer margin loans, and proprietary securities, commodities, and swaps positions. *Id.* The term ''high quality liquid assets'' or ''HQLA'' are defined under the Basel capital standard's liquidity coverage ratio (''LCR'') and generally consist of cash and specific classes of liquid securities. *See* BCBS, *LCR30 under the Basel capital standards,* available at: *https://www.bis.org/basel_framework/chapter/LCR/30.htm?tldate=20191231&inforce=2019121.* Generally, cash and securities that qualify as HQLA under the LCR would be allowable assets under Exchange Act rule 18a–1.

[238] Exchange Act rule 18a–3 does not require SBS Entities to post initial margin (though it does not prohibit the practice).

[239] *See* Capital and Margin Adopting Release, 84 FR at 43887–88.

[240] *See id.* at 43887.

[241] SIFMA Letter II at 7–17.

[242] *See* Better Markets Letter at 7–8 (comparing the differences between Exchange Act rule 18a–1 and the Basel capital standard and stating that ''not only are the France's capital requirements different from the SEC's in both form and substance, but the regulatory outcome is not comparable'').

[243] As discussed above, highly liquid assets under Exchange Act rule 18a–1 are also known as ''allowable assets'' and generally are consistent the LCR's HQLA.

liquidity—does not produce this regulatory outcome.[244] Therefore, an additional condition is needed to bridge the gap between these two capital standards and thereby achieve more comparable regulatory outcomes in terms of promoting liquid balance sheets for SBS Entities and Covered Entities.

However, in seeking to bridge this regulatory gap, the additional condition should take into account that Covered Entities are or will be subject to French and EU laws and measures designed to promote liquidity. As a commenter stated, Covered Entities are or will be subject to: (1) Requirements to hold an amount of HQLA to meet expected payment obligations under stressed conditions for thirty days (the ''LCR requirement''); [245] (2) requirements to hold a diversity of stable funding instruments sufficient to meet long-term obligations under both normal and stressed conditions (the ''NSFR requirements''); [246] (3) requirements to perform liquidity stress tests and manage liquidity risk (the ''internal liquidity assessment requirements''); [247] and (4) regular reviews of a Covered Entity's liquidity risk management processes by the French Authorities (the ''French Authority liquidity review process'').[248] These French and EU laws and measures will require Covered Entities to hold significant levels of liquid assets. However, the laws and measures on their own, do not impose a net liquid assets test. Therefore, an additional condition is necessary to supplement these requirements.

The Commission has taken into account the French and EU liquidity laws and measures discussed above in making a substituted compliance determination with respect to Exchange Act rule 18a–1, and in tailoring additional capital conditions designed to achieve comparable regulatory outcomes. The LCR, NSFR, and internal liquidity assessment requirements collectively will require Covered Entities to maintain pools of unencumbered HQLA to cover potential cash outflows during a 30-day stress period, to fund long-term obligations with stable funding instruments, and to manage liquidity risk. These requirements—coupled with the French Authorities' supervisory reviews of the liquidity risk management practices of Covered Entities—will require Covered Entities to hold significant levels of liquid assets. These requirements and measures in combination with the other capital requirements applicable to Covered Entities provide a starting foundation for making a positive substituted compliance determination with respect to the capital requirements of Exchange Act section 15F(e) and Exchange Act rule 18a–1.[249] However, more is needed to achieve a comparable regulatory outcome to the net liquid assets test of Exchange Act rule 18a–1.

For these reasons, the Order includes an additional capital condition that will impose a simplified net liquid assets test.[250] This simplified test will require the Covered Entity to hold more than one dollar of liquid assets for each dollar of liabilities. The simplified net liquid assets test—when coupled with the French and EU capital requirements,[251] LCR requirements, NSFR requirements, internal liquidity assessment requirements, and French Authority liquidity review process—is designed to produce a regulatory outcome that is comparable to the net liquid assets test of Exchange Act rule 18a–1 (*i.e.,* sufficient liquidity to cover liabilities and to promote the maintenance of highly liquid balance sheets).

In response to comments, the Commission has modified the first three prongs of the additional capital condition, as discussed below.[252] In particular, the first and third prongs are being combined into a single prong of the second additional capital condition.[253] Under this prong, the Covered Entity must maintain liquid assets (as defined in the capital condition) that have an aggregate market value that exceeds the amount of the Covered Entity's total liabilities by at least: (1) $100 Million before applying a deduction (specified in the capital condition); and (2) $20 million after applying the deduction.[254] Thus, the condition increases the scope of the liquid assets requirement so that it must cover all liabilities (rather than those maturing in 365 days as was contemplated by the Commission's questions in the Reopening Release).

These modifications align the first prong more closely to the $100 million tentative net capital requirement of Exchange Act rule 18a–1 applicable to SBS Entities approved to use models. As discussed above, Exchange Act rule 18a–1 requires SBS Entities that have been approved to use models to maintain at least *$100 million* in tentative net capital. And, tentative net capital is the amount that an SBS Entity's liquid assets exceed its total unsubordinated liabilities *before applying haircuts*. The first prong will require the Covered Entity to subtract total liabilities from total liquid assets. The amount remaining will need to equal or exceed $100 million. The modifications also align the condition more closely to the $20 million fixed-dollar minimum net capital requirement of Exchange Act rule 18a–1. As discussed above, net capital is calculated by *applying haircuts* (deductions) to tentative net capital and the fixed-dollar minimum requires that net capital must equal or exceed *$20 million*. The first prong will require the Covered Entity to subtract total liabilities from total liquid assets and then apply the deduction to the difference. The amount remaining after the deduction will need to equal or exceed $20 million.

For the purposes of the first prong of the second additional capital condition,

[244] The Basel capital standard does not preclude a firm from having more than a dollar of highly liquid assets for each dollar of unsubordinated liabilities. Thus, a firm operating pursuant to the standard may structure its assets and liabilities in a manner that achieves this result. However, the standard does not mandate this result. Rather, it will accommodate a firm that seeks to maintain this level of liquidity on its own accord.

[245] *See* CRR, Article 412(1), Regulation (EU) 2015/61.

[246] *See* CRR, Article 413 and Articles 428a to 428az introduced by Regulation (EU) 2019/876 (''CRR II''), Article 1(116).

[247] *See* CRD, Article 86, MFC Articles L. 511–41–1 B for credit institutions and L. 533–2–2 for investment firms; and Articles 148 to 186 of the Decree of 3 November 2014 on internal control.

[248] *See* SIFMA Letter II at 9–12.

[249] *See* Better Markets Letter at 8 (recommending that the Commission consider denying substituted compliance with respect to these Exchange Act capital requirements).

[250] *See* AFREF Letter at 1 (''The Commission should require that SBS entities who want to operate in the U.S. comply with the Net Liquid Assets test under the Exchange Act rule 18a–1 rather than the Basel capital standards'').

[251] *See, e.g.,* CRR, Part 1 (Own Funds, including Tier 1 capital) and Part 2 (Capital Requirements).

[252] *See* AFREF Letter at 1 (''The Commission should require that SBS entities who want to operate in the U.S. comply with the Net Liquid Assets test under the Exchange Act rule 18a–1 rather than the Basel capital standards''); SIFMA Letter at 17 (raising concerns that the use of the concept of ''allowable'' assets under Exchange Act rule 18a–1 in the first condition would require Covered Entities to re-categorize every asset on their balance sheets, which also pertains to the second condition, and seeking clarification on to how to calculate ''equity capital'' and allocate it to highly liquid assets equal to or greater than $100 million).

[253] The first prong of the proposed capital condition would have required a Covered Entity to maintain an amount of assets that are allowable under Exchange Act rule 18a–1, after applying applicable haircuts under the Basel capital standard, that equals or exceeds the Covered Entity's current liabilities coming due in the next 365 days. The second prong would have required the Covered Entity to make a quarterly record related to the first prong. The third prong would have required the Covered Entity to maintain at least $100 million of equity capital composed of highly liquid assets as defined in the Basel capital standard. *See* Reopening Release, 86 FR at 18345.

[254] *See* para. (c)(1)(iii)(A)(*1*) of the Order. The definition of ''liquid assets'' and the method of calculating the deductions are discussed below.

''liquid assets'' are defined as: (1) Cash and cash equivalents; (2) collateralized agreements; (3) customer and other trading related receivables; (4) trading and financial assets; and (5) initial margin posted by the Covered Entity to a counterparty or third-party (subject to certain conditions discussed below).[255] These categories of liquid assets are designed to align with assets that are considered allowable assets for purposes of calculating net capital under Exchange Act rule 18a–1.[256] Further, the first four categories of liquid assets also are designed to align with how Covered Entities categorize liquid assets on their financial statements. [257] In addition, the commenter who has raised concerns about the potential capital conditions made similar comments with respect to proposed capital conditions that would apply to SBS Entities in the United Kingdom.[258] The commenter's letter to the Commission included a table summarizing categories of liquid assets on the balance sheets of six UK dealers (the ''Balance Sheet Table'') that the commenter expects will register with the Commission as security-based swap dealers, and that do not have a prudential regulator and therefore would be subject to Exchange Act rule 18a–1.[259]

The first category of liquid assets is cash and cash equivalents.[260] These assets consist of cash and demand deposits at banks (net of overdrafts) and highly liquid investments with original maturities of three months or less that are readily convertible into known amounts of cash and subject to insignificant risk of change in value.[261] The second category of liquid assets is collateralized agreements.[262] These assets consist of secured financings where securities serve as collateral such as repurchase agreements and securities loaned transactions.[263] The third category of liquid assets is customer and other trading related receivables.[264] These assets consist of customer margin loans, receivables from broker-dealers, receivables related to fails to deliver, and receivables from clearing organizations.[265] The fourth category of liquid assets is trading and financial assets.[266] These assets consist of cash market securities positions and listed and over-the-counter derivatives positions.[267]

As discussed above, initial margin posted to a counterparty is treated differently under Exchange Act rule 18a–1 and the Basel capital standard, and commenters highlighted this difference.[268] The fifth category of liquid assets is initial margin posted by the Covered Entity to a counterparty or a third-party custodian, provided: (1) The initial margin requirement is funded by a fully executed written loan agreement with an affiliate of the Covered Entity; (2) the loan agreement provides that the lender waives re-payment of the loan until the initial margin is returned to the Covered Entity; and (3) the liability of the Covered Entity to the lender can be fully satisfied by delivering the collateral serving as initial margin to the lender.[269] As discussed above, one critical difference between Exchange Act rule 18a–1 and the Basel capital standard is that an SBS Entity cannot count as capital the amount of initial margin posted to a counterparty or third-party custodian unless it enters into a special loan agreement with an affiliate.[270] Under the Basel capital standard, a Covered Entity can count initial margin posted away as capital without the need to enter into a special loan arrangement with an affiliate. Consequently, to count initial margin posted away as a liquid asset for purposes of the second additional capital condition, the Covered Entity must enter into the same type of special agreement that an SBS Entity must execute to count initial margin as an allowable asset for purposes of Exchange Act rule 18a–1.[271]

If an asset does not fall within one of the five categories of ''liquid assets'' as defined in the Order,[272] it will be considered non-liquid, and could not be treated as a liquid asset for purposes of the second additional capital condition in the Order. For example, one commenter listed the following categories of non-liquid assets on the Balance Sheet Table: (1) ''Investments;'' (2) ''Loans;'' and (3) ''Other Assets.'' [273] Assets that fall into these categories could not be treated as liquid assets. The non-liquid ''investment'' category would include the Covered Entity's ownership interests in subsidiaries or other affiliates. The non-liquid ''loans'' category would include unsecured loans and advances. The non-liquid ''other'' assets category generally refers to assets that do not fall into any of the other categories of liquid or non-liquid assets. These non-liquid ''other'' assets would include furniture, fixtures, equipment, real estate, property, leasehold improvements, deferred tax assets, prepayments, and intangible assets.

As discussed above, the first prong of the second additional capital condition will require the Covered Entity to subtract total liabilities from total liquid assets and then apply a deduction (haircut) to the difference.[274] The amount remaining after the deduction

[255] *See* para. (c)(1)(iii)(B) of the Order.

[256] *See* notes 237 and 243, *supra* (describing allowable assets under Exchange Act rule 18a–1).

[257] As part of the application process, the French Authorities have stated that the only nonbank (*i.e.,* non-prudentially regulated) French dealers that will register with the Commission as security-based swap dealers are French investment firms will be re-authorized by the European Central Bank as credit institutions in 2021. *See* French Authorities' Application (Side Letter for Capital Requirements). These large investment firms publish annual audited financial statements. *See e.g.,* BofA Securities Europe SA 2020 Annual Report, available at: *https://investor.bankofamerica.com/regulatory-and-other-filings/subsidiary-and-country-disclosures.*

[258] *See* Letter from Kyle L. Brandon, Managing Director, Head of Derivatives Policy, SIFMA (May 3, 2021) (''SIFMA UK Letter'') at 9–20. This comment letter may be found on the Commission's website at: *https://www.sec.gov/comments/s7-04-21/s70421.htm.*

[259] The categories of liquid assets identified in the Balance Sheet Table are: (1) ''Cash/Cash Equivalents; (2) ''Collateralised Agreements;'' (3) ''Trade/Other Receivables; cash collateral pledged;'' and (4) ''Trading/Financial Assets.'' *See* SIFMA UK Letter, Appendix C.

[260] *See* para. (c)(1)(iii)(B)(*1*) of the Order.

[261] *See, e.g.,* International Financial Reporting Standards Foundation (''IFRS''), *IAS 7 Statement of Cash Flows* (defining ''cash'' as comprising cash on hand and demand deposits and ''cash equivalents'' as short-term, highly liquid investments that are readily convertible to known amounts of cash and which are subject to an insignificant risk of changes in value). *See also* Books and Records Adopting Release, 84 FR at 68673–74 (the section of the amended Part II of the FOCUS Report setting forth the assets side of the balance sheet and identifying cash as an allowable asset in Box 200).

[262] *See* para. (c)(1)(iii)(B)(*2*) of the Order.

[263] *See* Books and Records Adopting Release, 84 FR at 68673–74 (the section of the amended Part II of the FOCUS Report setting forth the assets side of the balance sheet and identifying securities borrowed as an allowable asset in Boxes 240 and 250 and securities purchased under agreements to resell as an allowable asset in Box 360).

[264] *See* para. (c)(1)(iii)(B)(*3*) of the Order.

[265] *See* Books and Records Adopting Release, 84 FR at 68673–74 (the section of the amended Part II of the FOCUS Report setting forth the assets side of the balance sheet and identifying fails to deliver as allowable assets in Boxes 220 and 230, receivables from clearing organizations as allowable assets in Boxes 280 and 290, and receivables from customers as allowable assets in Boxes 310, 320, and 330).

[266] *See* para. (c)(1)(iii)(B)(*4*) of the Order.

[267] *See* Books and Records Adopting Release, 84 FR at 68673–74 (the section of the amended Part II of the FOCUS Report setting forth the assets side of the balance sheet and identifying securities, commodities, and swaps positions as allowable assets in Box 12019).

[268] *See* Better Markets Letter at 7; AFREF Letter at 2. *See also* Reopening Release, 86 FR at 18344–45 (discussing the different treatment of initial margin posted to a counterparty).

[269] *See* para. (c)(1)(iii)(B)(*5*) of the order.

[270] *See* Capital and Margin Adopting Release, 84 FR at 43887–88.

[271] *Id.*

[272] *See* para. (c)(1)(iii)(B) of the Order.

[273] *See* SIFMA UK Letter, Appendix C.

[274] *See* para. (c)(1)(ii)(A)(*1*) of the order.

will need to equal or exceed $20 million. The method of calculating the amount of the deduction relies on the calculations Covered Entities must make under the Basel capital standard.[275] In particular, under the Basel capital standard, Covered Entities must risk-weight their assets. This involves adjusting the nominal value of each asset based on the inherent risk of the asset. Less risky assets are adjusted to lower values (*i.e.,* have less weight) than more risky assets. As a result, Covered Entities must hold lower levels of regulatory capital for less risky asset and higher levels of capital for riskier assets. Similarly, under Exchange Act rule 18a–1, less risky assets incur lower haircuts than riskier assets and, therefore, require less net capital to be held in relation to them. Consequently, the process of risk-weighting assets under the Basel capital standard provides a method to account for the inherent risk in an asset held by a Covered Entity similar to how the haircuts under the Exchange Act rule 18a-1 account for the risk of assets held by SBS Entities. For these reasons, it is appropriate to use the process of risk-weighting assets under the Basel capital standard to determine the amount of the deduction (haircuts) under the first prong of the second additional capital condition.

Under the Basel capital standard, Covered Entities must hold regulatory capital equal to at least 8% of the amount of their risk-weighted assets.[276] Therefore, the deduction (haircut) required for purposes of the first prong of the second additional capital condition is determined by dividing the amount of the Covered Entity's risk-weighted assets by 12.5 (*i.e.,* the reciprocal of 8%).[277] In sum, the Covered Entity must maintain an excess of liquid assets over total liabilities that equals or exceeds $100 million before the deduction (derived from the firm's risk-weighted assets) and $20 million after the deduction. [278]

The second prong of the second additional capital condition requires the Covered Entity to make and preserve for three years a quarterly record that: (1) Identifies and values the liquid assets maintained pursuant to the first prong; (2) compares the amount of the aggregate value the liquid assets maintained pursuant to the first prong to the amount of the Covered Entity's total liabilities and shows the amount of the difference between the two amounts (''the excess liquid assets amount''); and (3) shows the amount of the deduction required under the first prong and the amount that deduction reduces the excess liquid assets amount.[279] This prong has been modified from the proposed Order to conform to the modifications to the first and third prongs of the proposed capital condition discussed above (*i.e.,* combining them into a single prong that imposes a simplified net liquid assets test). Under the Order, the quarterly record will include details showing whether the Covered Entity is meeting the $100 million and $20 million requirements of the first prong.

The third prong of the second additional capital condition requires the Covered Entity to notify the Commission in writing within 24 hours in the manner specified on the Commission's website if the Covered Entity fails to meet the requirements of the first prong and include in the notice the contact information of an individual who can provide further information about the failure to meet the requirements.[280] As discussed above, the first additional capital condition requires the Covered Entity to apply substituted compliance with respect to notification requirements of Exchange Act rule 18a–8 relating to capital.[281] A Covered Entity applying substituted compliance with respect to Exchange Act rule 18a–8 must simultaneously submit to the Commission any notifications relating to capital that it must submit to the French authorities. However, French and EU notification requirements do not address a failure to adhere to the simplified net liquid assets test required by the first prong of the second additional capital condition. Moreover, due to the differences between Exchange Act rule 18a–1 and the Basel capital standard discussed above, a Covered Entity could fall out of compliance with the requirements of the first prong but still remain in compliance with the requirements of the Basel capital standard. Accordingly, the third prong requires the Covered Entity to notify the Commission if the firm fails to meet the requirements of the first prong. This will alert the Commission of potential issues with the Covered Entity's financial condition that could pose risks to the firm's customers and counterparties.

The fourth prong of the additional capital condition in the proposed Order would have required the Covered Entity to include its most recently filed statement of financial condition (whether audited or unaudited) with its initial notice to the Commission of its intent to rely on substituted compliance. No commenters raised specific concerns with this condition and the Order includes it as proposed, but now it is the fourth prong of the *second* additional capital condition.[282]

The commenter who opposed additional capital conditions stated that their burdens would be disruptive to market participants and could cause Covered Entities to exit the U.S. security-based swap market.[283] However, this may not be case. For example, the commenter stated that the Covered Entities expected to register with the Commission transact predominantly in securities and derivatives and do not extensively engage in unsecured lending or other activities more typical of banks.[284] The commenter based this statement on a high-level review of public information about the balance sheets of six Covered Entities undertaken to create the

[275] *See* BCBS, *Risk-based capital requirements (RBC20),* available at: *https://www.bis.org/basel_framework/chapter/RBC/20.htm?inforce=20191215&published=20191215.*

[276] *Id.*

[277] *See* para. (c)(1)(iii)(C) of the Order. The Commission acknowledges that a Covered Entity's risk-weighted assets will include components in addition to market and credit risk charges (*e.g.,* operational risk charges). However, the Commission expects the combined market and credit risk charges will make up the substantial majority of the risk-weighted assets. In addition, the Commission believes that this method of calculating the deduction in the first prong of the second additional capital condition is a reasonable approach in that it addresses market and credit risk similar to the process used by security-based swap dealers authorized to use internal models to compute market and credit risk deductions under Exchange Act rule 18a–1. *See, e.g.,* Exchange Act rule 18a–1(e) (prescribing requirements to calculate market and credit risk charges, including use of an 8% multiplication factor for calculating the credit risk charges).

[278] For example, assume a Covered Entity has total assets of $600 million (of which $595 million are liquid and $5 million are illiquid) and total liabilities of $450 million. In this case, the Covered Entity's liquid assets would exceed total liabilities by $145 million ($590 million minus $450 million) and, therefore, the Covered Entity would have excess liquid assets greater than $100 million as required by the first prong of the second additional capital condition. Assume further that the Covered Entity's risk-weighted assets under the Basel capital standard equal $400 million. In this case, the Covered Entity's deduction would equal $32 million ($400 million divided by 12.5). Subtracting $32 million from $145 million leaves $113 million, which exceeds $20 million. Therefore, the Covered Entity would meet the second requirement of the first prong of the second additional capital condition.

[279] *See* para. (c)(1)(iii)(A)(*2*) of the order.

[280] *See* para. (c)(1)(iii)(A)(*3*) of the Order.

[281] *See* para. (c)(1)(ii) of the Order.

[282] *See* para. (c)(1)(iii)(A)(*4*) of the Order. As discussed above, a commenter objected to the capital conditions generally and provided specific comments with respect to the first three conditions, but not the fourth condition. *See* SIFMA Letter at 9–20. This commenter did support the fourth condition as part of its recommended incremental approach to implementing the capital conditions. *See* SIFMA Letter at 19–20.

[283] *See* SIFMA Letter at 19.

[284] *See* SIFMA Letter at 10–11.

Balance Sheet Table.[285] Based on this review, the commenter stated that the ''vast majority of each firm's total assets consists of cash and cash equivalents, collateralized agreements, trade and other receivables, and other trading and financial assets. The commenter characterized these assets as being ''liquid.'' The commenter stated further that the amount of illiquid assets held by these firms as a proportion of their balance sheets is comparable to the proportion of illiquid assets held by U.S. broker-dealers. The commenter also stated that the long-term debt, subordinated debt, and equity of the Covered Entities, as a proportion of their total liabilities and equity, also was comparable to U.S. broker-dealers. Moreover, based on the Balance Sheet Table and the staff's analysis of the public financial reports of the major investment firms regulated by the Prudential Regulatory Authority (''PRA'') in the United Kingdom (*i.e.,* a PRA-designated investment firm) and a large investment firm in France, these firms report total liquid assets that exceed total liabilities and, in most cases, substantially in excess of $100 million.[286]

This information suggests that Covered Entities may be able to meet the second additional capital condition without having to significantly adjust their assets, liabilities, and equity. Moreover, the modifications to the second additional capital condition that incorporate how Covered Entities categorize liquid and illiquid assets and calculate risk-weighted assets, will allow them to use existing processes to derive the measures needed to adhere to the condition. Therefore, while the condition imposes a simplified net liquid assets test and associated recordkeeping requirement, it may not cause Covered Entities to withdraw from the U.S. security-based swap market. Nonetheless, it is possible that the simplified net liquid assets test and associated recordkeeping burden could cause a Covered Entity to withdraw from the U.S. security-based swap market. However, as discussed above, this additional capital condition is designed to produce a comparable regulatory outcome with respect to SBS Entities subject to Exchange Act rule 18a–1 and Covered Entities applying substituted compliance with respect to that rule.

In response to a specific request for comment in the Reopening Release, a commenter stated that the capital conditions would not be necessary if the balance sheets of the Covered Entities seeking to apply substituted compliance with respect to Exchange Act rule 18a–1 were similar to the balance sheets of U.S. broker-dealers.[287] However, the Commission also sought comment on whether the capital conditions would serve to ensure that these firms do not engage in non-securities business activities that could impair their liquidity.[288] Two commenters expressed support for the capital conditions.[289] The fact that today certain Covered Entities have liquid balance sheets does not mean this will hold true in the future or with respect to other potential registrants. For these reasons, it is appropriate to include additional conditions with respect to applying substituted compliance to Exchange Act rule 18a–1.

It would not be appropriate to take a more incremental approach to the additional capital conditions as suggested by a commenter.[290] Substituted compliance is premised on comparable regulatory outcomes. As discussed above, the additional capital condition is designed to supplement French and EU capital laws in order to achieve a comparable regulatory outcome in terms of the net liquid assets test of Exchange Act rule 18a–1. Delaying the implementation of the additional capital condition would mean that Covered Entities are operating as registered security-based swap dealers under a capital standard that does impose the net liquid assets test. This would be inconsistent with the objective of substituted compliance and could increase risk to the U.S. security-based swap markets and participants in those markets. Moreover, the modifications to the capital conditions discussed above may ease the implementation burdens.

In addition, the Commission does not believe a commenter's suggestion for an alternative capital condition requiring a Covered Entity to maintain $100 million of HQLA as defined in the LCR requirements would be adequate in terms of achieving comparable regulatory outcomes with Exchange Act rule 18a–1.[291] The Balance Sheet Table and public financial reports of investment firms in the UK and France indicates that Covered Entities have total liabilities of many billions of dollars.[292] A condition requiring $100 million in highly liquid assets would not cover these liabilities and would not impose a net liquid assets test.

Finally, the Commission has modified the citations to French and EU laws in the capital section of the Order in response to comment and further analysis.[293] In response to comments, the capital section of the Order does not cite ''recitals'' because they are not part of a legally binding regulation.[294]

The Commission agrees with the comments that the specific provisions to the CRR citied in the proposed Order are not comprehensive .[295] In response, the Commission has modified the final ordering language to use more comprehensive citations to the CRR (including the specific CRR provisions cited in the proposed Order), as the capital analysis includes only discussion of entities that are fully subject to CRR and CRD IV.[296] In addition, this commenter recommended that the Commission modify the final ordering language to qualify the citations to the CRR with a reference to waivers and permissions.[297] In response, the specific provisions in the CRR referenced in the capital comparability analysis were analysed without reference to waivers or permissions, and the condition states that the Covered Entity must be subject to and comply with these specific capital requirements. Therefore, the more comprehensive references to the CRR in the final order are cited without reference to waivers or permissions.

Further, the Commission agrees with the commenter that some of the citations do not relate to requirements imposed on Covered Entities, but generally relate to the powers of relevant authorities. In these cases, citations in the ordering language have been deleted or modified to reference requirements that a Covered Entity is subject to and must comply with.[298]

[285] *See* SIFMA Letter at 10–11, Appendix C.

[286] The Bank of England publishes a list of PRA-designated investment firms. This list is available at: *https://www.bankofengland.co.uk/prudential-regulation/authorisations/which-firms-does-the-pra-regulate.*

[287] *See* SIFMA Letter II at 8; Reopening Release, 86 FR at 18345.

[288] Reopening Release, 86 FR at 18345.

[289] *See* Better Markets Letter at 7–8; AFREF Letter at 1–2.

[290] *See* SIFMA Letter II at 16–17.

[291] *See* SIFMA Letter II at 16.

[292] *See* SIFMA UK Letter, Appendix C.

[293] SIFMA Letter II at Appendix A.

[294] SIFMA Letter II, Appendix A.

[295] SIFMA Letter II, Appendix A.

[296] French Authorities' Application (Side Letter for Capital Requirements) at p.4. More specifically, in the final Order, the Commission is including references to the CRR to read: CRR, Part One (General Provisions) Article 6(1), Part Two (Own Funds), Part Three (Capital Requirements), Part Four (Large Exposures), Part Five (Exposures to Transferred Credit Risk), Part Six (Liquidity), and Part Seven (Leverage).

[297] SIFMA Letter II, Appendix A.

[298] More specifically, in the final order, the Commission is: (1) Deleting BRRD Articles 27(1), 31(2), 31(1)(a) and (5), and 32(5); (2) deleting CRD Articles 97, 98(1)(e), 98(6), 99, 100(1), 102(1), 104, 104(1), 105. 142(4) and narrowing the scope of

In response to the comment that the reference to MFC Article L. 511–13 be deleted because it relates to governance requirements and is beyond the scope of capital requirements, the Commission agrees. Therefore, the Commission is deleting this reference from the Order.

Further, in response to comments to insert the phrase ''as applicable'' in certain places in the capital condition, the Commission is not modifying the Order to ensure Covered Entities remain subject to and comply with the laws and regulations cited in the capital condition. The Commission acknowledges that some of the citations to the French laws apply only to specific types of institutions (*i.e.,* credit institutions or investment firms).[299] In such cases, a Covered Entity would comply with the relevant citation in the MFC article that corresponds to its entity type.

In response to the comment that the Commission narrow the scope of references to CRD Articles 129 (Requirement to maintain a capital conservation buffer), 130 (Requirement to maintain an institution-specific countercyclical capital buffer), and 131 (Global and other systemically important institutions) because some of the paragraphs do not impose any obligations on firms, the Commission disagrees and is retaining these citations in the Order. These references were cited in the French Authorities' Application in their entirety with reference to the requirement that ''institutions must maintain certain capital buffers above the minimum 8 percent capital level composed of Common Equity Tier 1 capital instruments.'' [300] Therefore, it is appropriate to retain these citations in the Order.

In response to the comments that the Commission update the reference to BRRD Article 45(6), since it had been amended, the Commission is retaining the reference, since the references are to citations in the French Authorities' Application.[301] In addition, the term BRRD means Bank Recovery and Resolution Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014, as amended from time to time. Therefore, amendments to the BRRD are already included in the definition and covered by the capital conditions in the Order.[302]

In addition, in response to a recommendation to delete references to the EMIR margin requirements, the Commission is retaining the references to the EMIR Margin RTS requirements as the French Authorities' Application states ''if liquidation did occur, EU regulations also protect counterparties and promote continued market liquidity through margin requirements.'' [303] Finally, the references to the EMIR Margin RTS and the final references in the capital ordering language contribute to the conclusion that French and EU laws produces a comparable regulatory outcome to the capital requirements under the Exchange Act.

2. Margin

The Commission's preliminary view, based on the French Authorities' Application and the Commission's review of applicable provisions, was that relevant French and EU margin requirements would produce regulatory outcomes that are comparable to those associated with Exchange Act margin requirements without the need for additional conditions.[304] For example, in adopting final margin requirements for non-cleared security-based swaps, the Commission modified the rule to more closely align it with the margin rules of the Commodity Futures Trading Commission and the U.S. prudential regulators and, in doing so, with the recommendations made by the BCBS and the Board of the International Organization of Securities Commissions (''IOSCO'') with respect to margin requirements for non-centrally cleared derivatives.[305]

Exchange Act rule 18a–3 and the French and EU margin rules require firms to collect liquid collateral from a counterparty to cover variation and/or initial margin requirements.[306] Both sets of rules also require firms to deliver liquid collateral to a counterparty to cover variation margin requirements. Under both sets of rules, the fair market value of collateral used to meet a margin requirement must be reduced by a haircut.[307] Further, both sets of rules permit the use of a model (including a third party model such as ISDA's SIMM™ model) to calculate initial margin.[308] The initial margin model under both sets of rules must meet certain minimum qualitative and quantitative requirements, including that the model must use a 99 percent, one-tailed confidence level with price changes equivalent to a 10-day movement in rates and prices.[309] Both sets of rules have common exceptions to the requirements to collect and/or post initial or variation margin, including exceptions for certain commercial end users, the Bank for International Settlements, and certain multilateral development banks.[310] Both sets of rules also permit a threshold below which initial margin is not required to be collected and incorporate a minimum transfer amount.[311]

In the French Substituted Compliance Notice and Proposed Order, the Commission stated substituted compliance with respect to the margin requirements accordingly would be conditioned on Covered Entities being subject to those French and EU provisions that, the Commission has determined, in the aggregate, establish a framework that produces outcomes comparable to those associated with the

Article 142 to (1) and (2); (3) deleting MFC Articles L. 511–15; 511–41–1 A(XIV), L. 511–41–3.II–IV., L. 511–41–1 C, L. 511–41–3, L. 511–41–4, L. 511–41–5, L. 511–42, L. 532–6, L. 533–2–3, L. 612–24, R. 612–30, L. 612–32, R. 612–32, L. 612–33.I, L. 612–33.II, L. 612–40, and L. 613–50.I, L. 631–2–1, narrowing the reference to L. 613–49 to 613–49I.; (4) deleting the reference to Article 10 of the Decree of 3 November 2014 on internal control; (5) deleting the Ministerial Order on the Supervisory Review and Evaluation Process, articles 6 through 10; and (6) deleting Articles 37, 38, 63, and 64 of Decree of 3 November 2014 relating to capital buffers.

[299] For example, Article L. 511–41–1–B of the MFC implements Article 73 of CRD (Internal Capital) for credit institutions, and MFC article L. 533–2–2 implements it for investment firms.

[300] French Authorities' Application, Side Letter for Capital Requirements at n.13 (and accompanying text).

[301] *See* SIFMA Letter II at Appendix A.

[302] The commenter also recommended deleting CRD Article 23 since it has been replaced by recent amendments to CRD. The proposed Order does not cite Article 23 of the CRD. Therefore, this comment is moot.

[303] French Authorities' Application, Side Letter for Capital Requirements at 22. For example, the EMIR Margin RTS require a Covered Entity to segregate initial margin from the firm's assets by either placing it with a third-party holder or custodian or via other legally binding arrangements, making the initial margin remote in the case of the firm's default or insolvency. *Id.*

[304] French Substituted Compliance Notice and Proposed Order, 85 FR at 85726.

[305] *Id.,* 85 FR at 85726, n.50; *See* Capital and Margin Adopting Release, 84 FR at 43908–09. *See also* BCBS/IOSCO, Margin Requirements for Non-centrally Cleared Derivatives (April 2020), available at *https://www.bis.org/bcbs/publ/d499.pdf* (''BCBS/IOSCO Paper''). The French and EU margin requirements also are based on the recommendation in the BCBS/IOSCO Paper.

[306] *See* 17 CFR 240.18a–3(c)(1)(ii) and French Authorities' Application at 27–28.

[307] *See* 17 CFR 240.18a–3(c)(1)(ii) and French Authorities' Application at 40–43.

[308] *See* 17 CFR 240.18a–3(d)(2)(i) and French Authorities' Application at 12–20.

[309] *See* 17 CFR 240.18a–3(d)(2)(i) and French Authorities' Application at 12. The Commission must approve the use of an initial margin model. 17 CFR 240.18a–3(d)(2)(i). EMIR Article 11(15) directs European supervisory authorities to develop regulatory technical standards under which initial margin models have to be approved (initial and ongoing approval). EU requirements currently provide that, upon request, counterparties using an initial margin model shall provide the regulators with any documentation relating to the risk management procedures relating to such model at any time. EMIR Margin RTS, Article 2(6).

[310] *See* 17 CFR 240.18a–3(c)(1)(iii) and French Authorities' Application at 54–65.

[311] *See* 17 CFR 240.18a–3(c)(1)(iii) and French Authorities' Application at 54–65.

requirements under the Exchange Act rule 18a–3.[312] Commenters supported the Commission's proposed approach for substituted compliance with respect to margin requirements.[313]

One commenter suggested technical comments with respect to refining the French and EU laws cited in the proposed Order.[314] In particular, this commenter recommended that the Commission (1) delete the citations to the CRR; (2) narrow the scope of the reference to EMIR Article 11 to Article 11(3); and (3) insert the phrase ''as applicable'' before the citations to the French laws.[315] The Commission disagrees with the commenter that the scope of the citation to EMIR Article 11 should be narrowed. Other provisions of EMIR Article 11 relate to margin requirements, including the provisions regarding intragroup transactions. Therefore, the Commission is not modifying this citation in the final order. With respect to the suggestion by the commenter to delete references to the CRR requirements, the Commission concludes that the requirements which were set out in the proposed Order, contribute to the conclusion that French and EU law produce a comparable regulatory outcome to the margin requirements under the Exchange Act.[316] Finally, the Commission is not modifying the Order to insert the phrase ''as applicable'' because it is overly broad. The Commission acknowledges that some of the citations to the French laws apply only to specific types of institutions (*i.e.,* credit institutions or investment firms).[317] In such cases, a Covered Entity would comply with the relevant citation in the MFC article that corresponds to its entity type. For the foregoing reasons, the first margin condition requires the covered entity to be subject to and comply with certain identified French and EU margin requirements.[318]

The proposed Order did not contain any additional conditions for substituted compliance with respect to the margin requirements of Exchange Act section 15F(e) and Exchange Act rule 18a–3. The Commission, however, requested comment on whether there were any conditions that should be applied to substituted compliance for the margin requirements to promote comparable regulatory outcomes.[319] As discussed below, in response to comments received, the Order includes two additional margin conditions designed to produce comparable regulatory outcomes with respect to collecting variation and initial margin from counterparties.[320]

In particular, a commenter raised general concerns with the Commission's regulatory outcomes approach to substituted compliance, and suggested additional general principles that the Commission should consider in evaluating applications for substituted compliance.[321] This commenter believed regulatory arbitrage within and outside the United States was one of the key factors that led to and exacerbated the 2008 financial crisis, and stated that the Dodd-Frank Act was enacted in response, which includes the Commission's authority to promulgate capital, margin, and other rules for non-cleared security-based swaps ''to reduce the possibility and severity of another crisis related to excessive buildup of risk in the swaps markets.'' [322]

The Commission responds to the comments on the Commission's approach to substituted compliance in part II.D.2 above. However, as stated above, the commenter raises concerns about regulatory arbitrage and the potential impacts of differences in requirements that merit re-consideration of whether additional margin conditions are needed to produce comparable regulatory outcomes.[323] When proposing margin requirements for non-cleared security-based swaps and swaps.'' [324] Further, the comparability criteria for margin requirements under Exchange Act rule 3a71–6 provides that prior to making a substituted compliance determination, the Commission intends to consider (in addition to any conditions imposed) whether the foreign financial regulatory system requires registrants to adequately cover their current and future exposure to OTC derivatives counterparties, and ensures registrants' safety and soundness, in a manner comparable to the applicable provisions arising under the Exchange Act and its rules and regulations.[325] In adopting this comparability criteria for margin requirements, the Commission stated that obtaining collateral is one of the ways OTC derivatives dealers manage their credit risk exposure to OTC derivatives counterparties.[326]

To address the risk of uncollateralized exposures, Exchange Act rule 18a–3 requires SBS entities without a prudential regulator to collect variation margin from all counterparties, including affiliates, unless an exception applies.[327] Under the French and EU margin requirements, there are exceptions from the variation margin requirements for certain intragroup transactions (*i.e.,* transactions between affiliates).[328] In addition, Exchange Act rule 18a–3 requires firms to collect initial margin from all counterparties, unless an exception applies.[329] This initial margin requirement under Exchange Act rule 18a–3 requires the firm to collect initial margin from a financial counterparty such as a hedge fund without regard to whether the counterparty has material exposures to non-cleared security-based swaps and uncleared swaps. In contrast, the French and EU margin requirements do not require Covered Entities to collect initial margin from financial counterparties, if their notional exposure to non-centrally

[312] French Substituted Compliance Notice and Proposed Order, 85 FR at 85726.

[313] FBF Letter I at 4; SIFMA Letter I at 13.

[314] SIFMA Letter II, Appendix A.

[315] SIFMA Letter II, Appendix A.

[316] The references to the CRR were included in the comparability assessment for margin requirements, and in the Commission's view the holistic approach for comparing regulatory outcomes should seek to reflect the whole of a jurisdiction's relevant requirements, rather than select subsets of those requirements.

[317] For example Article L. 511–41–1–B of the MFC implements Article 73 of CRD (Internal Capital) for credit institutions, and MFC article L. 533–2–2 implements it for investment firms.

[318] *See* para. (c)(2)(i) of the order. The first margin condition requires that Covered Entities must be subject to and comply with EMIR article 11; EMIR Margin RTS; CRR articles 103, 105(3), 105(10), 111(2), 224, 285, 286, 286(7), 290, 295, 296(2)(b), 297(1), 297(3), and 298(1); MiFID Org Reg. article 23(1); CRD articles 74 and 79(b); MFC articles L. 511–41–1–B, L. 533–2–2, L. 533–29, I al. 1, and L. 511–55 al. 1; and Decree of 3 November 2014 on internal control, article 114.

[319] French Substituted Compliance Notice and Proposed Order, 85 FR at 85737.

[320] *See* paras. (c)(2)(ii) and (iii) of the order.

[321] Better Markets Letter at 3.

[322] Better Markets Letter at 2.

[323] Better Markets Letter at 2–3.

[324] *See* Capital, Margin, and Segregation Requirements for Security-Based Swap Dealers and Major Security-Based Swap Participants and Capital Requirements for Broker-Dealers; Proposed Rule, Exchange Act Release No. 68071 (Oct. 18, 2021), 77 FR 70214, 70258 (Nov. 23, 2012).

[325] *See* 17 CFR 240.3a71–6(d)(5)(i) and (ii).

[326] *See* Capital and Margin Adopting Release, 84 FR at 43949 (''Obtaining collateral is one of the ways OTC derivatives dealers manage their credit risk exposure to OTC derivatives counterparties. Prior to the financial crisis, in certain circumstances, counterparties were able to enter into OTC derivatives transactions without having to deliver collateral. When ''trigger events'' occurred during the financial crisis, those counterparties faced significant liquidity strains when they were required to deliver collateral.) *Id.*

[327] *See* 17 CFR 240.18a–3(c)(ii)(A)(*1*) and (*2*).

[328] French Authorities' Application at 60.

[329] *See* 17 CFR 240.18a–3(c)(ii)(B).

cleared derivatives does not exceed a certain threshold on a group basis.[330]

In some cases these differences may result in a Covered Entity not being adequately collateralized to cover its current or future exposure to these counterparties with respect to its OTC derivatives transactions. In addition, differences in the counterparty exceptions could potentially incentivize market participants to engage in non-cleared security-based swap transactions outside of the United States.[331] Consequently, it is appropriate to impose additional margin conditions to produce comparable regulatory outcomes in terms of counterparty exceptions between Exchange Act rule 18a–3 and the French and EU requirements.

The first additional condition addresses differences in the counterparty exceptions with respect to variation margin. It requires a Covered Entity to collect variation margin, as defined in the EMIR Margin RTS, from a counterparty with respect to a transaction in non-cleared security-based swaps, unless the counterparty would qualify for an exception under Exchange Act rule 18a–3 from the requirement to deliver variation margin to the Covered Entity.[332] This condition defines variation margin by referencing EMIR Margin RTS to facilitate implementation of the condition by Covered Entities. Under this condition, for example, Covered Entities would be required to collect variation margin from their affiliates, but would be permitted to comply with all other French and EU margin requirements, including calculation, collateral, documentation, and timing of collection requirements. The first additional condition will close the gap between the counterparty exceptions of Exchange Act rule 18a–3 and the French and EU margin rules with respect to variation margin.

The second additional condition addresses differences in the counterparty exceptions with respect to initial margin. It requires a Covered Entity to collect initial margin, as defined in the EMIR Margin RTS, from a counterparty with respect to transactions in non-cleared security-based swaps, unless the counterparty would qualify for an exception under Exchange Act rule 18a–3 from the requirement to deliver initial margin to Covered Entity.[333] The condition defines initial margin by referencing EMIR Margin RTS to facilitate implementation of the condition by Covered Entities. Under this condition, for example, Covered Entities would be required to collect initial margin from their certain counterparties, but would be permitted to comply with all other French and EU margin requirements, including calculation, collateral, documentation, and timing of collection requirements. The second additional condition will close the gap between the counterparty exceptions of Exchange Act rule 18a–3 and the French and EU margin rules with respect to initial margin.

Finally, for the reasons discussed above in part III.B.2.e of this release, the third additional condition is that the Covered Entity applies substituted compliance with respect to Exchange Act rules 18a–5(a)(12) (a record making requirement).[334] This record making requirement is directly linked to the margin requirements of Exchange Act rule 18a–3. The UK Proposed Order conditioned substituted compliance with respect to this record making requirement on the Covered Entity applying substituted compliance with respect to Exchange Act rule 18a–3.[335] This additional condition is designed to provide clarity as to the Covered Entity's obligations under this record making requirement when applying substituted compliance with respect to Exchange Act rule 18a–3 pursuant this Order.

VI. Substituted Compliance for Internal Supervision and Compliance Requirements

A. Proposed Approach

The French Authorities' Application further requested substituted compliance in connection with requirements relating to:

- Internal supervision—Diligent internal supervision and conflict of interest provisions that generally require SBS Entities to establish, maintain and enforce supervisory policies and procedures that reasonably are designed to prevent violations of applicable law, and implement certain systems and procedures related to conflicts of interest.
- Chief compliance officers—Chief compliance officer provisions that generally require SBS Entities to designate individuals with the responsibility and authority to establish, administer and review compliance policies and procedures, to resolve conflicts of interest, and to prepare and certify annual compliance reports to the Commission.
- Additional Exchange Act section 15F(j) requirements—Certain additional requirements related to information-gathering and antitrust prohibitions.[336]

Taken as a whole, these requirements generally help to advance SBS Entities' use of structures, processes and responsible personnel reasonably designed to promote compliance with applicable law, identify and cure instances of noncompliance, and manage conflicts of interest.

In proposing to provide conditional substituted compliance in connection with this part of the French Authorities' Application, the Commission preliminarily concluded that the relevant French and EU requirements in general would produce comparable regulatory outcomes by providing that French SBS Entities have structures and processes that reasonably are designed to promote compliance with applicable law and to identify and cure instances of non-compliance and manage conflicts of interest. Substituted compliance under the proposed Order was to be conditioned in part on SBS Entities being subject to and complying with specified French and EU provisions that in the aggregate produce regulatory outcomes that are comparable to those associated with those internal supervision, compliance and related requirements under the Exchange Act.[337]

Under the proposed Order, substituted compliance was to be subject to certain additional conditions to help ensure the comparability of regulatory outcomes. First, substituted compliance in connection with the internal supervision requirements

[330] French Authorities' Application at 7. These thresholds are being phased-in with the last initial margin threshold set at EUR 8 billion.

[331] The Commission recognizes there are also cases where the French and EU margin rules are more restrictive than Exchange Act rule 18a–3. French and EU margin rules require Covered Entities to post initial margin to covered counterparties, while the Exchange Act rule 18a–3 would permit posting but not require it. In addition, French and EU margin rules also require a Covered Entity to collect (and post) initial margin to financial and non-financial counterparties if their notional exposure to non-centrally cleared derivatives exceeds a certain threshold on a group basis. In contrast, Exchange Act rule 18a–3 does not require (but permits) a nonbank security-based swap dealer to collect initial margin from counterparties that are financial market intermediaries. 17 CFR 240.18a–3(c)(1)(iii)(B). The comparability analysis, however, focuses on determining whether the French and EU margin rules are comparable to Exchange Act rule 18a–3.

[332] *See* para. (c)(2)(ii) of the order.

[333] *See* para. (c)(2)(iii) of the order.

[334] *See* para. (c)(2)(iv) of the Order.

[335] *See* UK Substituted Compliance Notice and Proposed Order, 86 FR at 18396–98, 18416. The Commission sought comment in the Reopening Release on whether this approach should be taken in the final Order. *See* Reopening Release, 86 FR at 18348.

[336] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85726–27.

[337] *See id.* at 85727 n.55.

would be conditioned on the Covered Entities complying with applicable French and EU supervisory and compliance provisions *as if* those provisions also require the Covered Entities to comply with applicable requirements under the Exchange Act and the other conditions of the Order. This condition was intended to reflect that, even with substituted compliance, Covered Entities still directly would be subject to a number of requirements under the Exchange Act and conditions of the Order that fall outside the ambit of French and EU internal supervision and compliance requirements.[338]

For similar reasons, the proposed Order conditioned substituted compliance in connection with compliance report requirements on the Covered Entity annually providing the Commission with certain compliance reports required pursuant to regulations under MiFID Org Reg 22(2)(C). Those reports must be in English, be accompanied by a certification under penalty of law that the report is accurate and complete, and would have to address the SBS Entity's compliance with other conditions to the substituted compliance order.[339] In addition, substituted compliance under the proposal would not extend to antitrust provisions under the Exchange Act, based on the preliminary conclusion that allowing an alternative means of compliance would not lead to comparable regulatory outcomes.[340]

B. Commenter Views and Final Provisions

Following the release of the proposed Order, commenters requested that the conditions to substituted compliance in connection with the internal supervision and compliance requirements be narrowed by eliminating references to recordkeeping requirements pursuant to MiFID, and CRD provisions related to the treatment of risk. In the commenter's view, compliance with those provisions are not necessary to justify substituted compliance.[341]

Partially in response to the initial comments to the proposed Order, the Reopening Release requested comment on a revision to the Order to include two additional prerequisites in connection with internal supervision: CRR articles 286 through 288 and 293, which address counterparty credit risk and risk management generally; and EMIR Margin RTS article 2, which addresses collateral-related risk management procedures.[342] The proposed additions were intended to promote analogous compliance goals as the other requirements identified within paragraph (d)(3) of the proposed Order.[343] The only commenter to address the proposed additions did not support them.[344]

Commenters requested additional alterations to the internal supervision conditions aside from those identified in the Reopening Release. Specifically, commenters recommended changes to the compliance report certification language described in paragraph (d)(2)(ii)(B) of the proposed Order, that ''under penalty of law, the report is accurate and complete,'' to language ''consistent with the requirement of the linked Exchange Act rule, Exchange Act rule 15Fk–1(c)(2)(ii)(D).'' [345] Additionally, one commenter requested that the condition requiring Covered Entities to provide certain reports pursuant to MiFID Org Reg Article 22(2)(c) should ''apply solely to the extent [the reports] are related to a Covered Entity's business as an SBS Entity.'' [346] Commenters also requested that the timing of compliance report submissions for reports required under MiFID Org Reg Article 22(2)(c) be ''15 days after the Covered Entity completes its annual MiFID report as required by MiFID'' [347] and alternatively ''15 days after [the report's] submission to the AMF in April each year.'' [348]

The Commission has considered commenter's views, and is making changes to the final Order related to compliance report certification, the timing of submission of compliance reports to the Commission, and certain French and EU predicates to substituted compliance. In large part, however, the Commission is adopting this part of the Order as it was proposed.

1. French and EU Predicate Conditions to Internal Supervision and Compliance Requirements

In the French Substituted Compliance Notice and Proposed Order, the Commission preliminarily proposed to make a positive substituted compliance determination for supervisory and compliance requirements conditioned on Covered Entities complying with specified French and EU requirements that promote internal supervision within those entities.[349] A commenter requested that the Commission not require a Covered Entity to be subject to and comply with certain of these specified requirements because the commenter argued the provisions were related to risk management and therefore should be deleted or addressed elsewhere or alternatively the provisions do not correspond to, and go beyond, the requirements of the Exchange Act.[350] The Commission details below its consideration of these comments.

One commenter objected to the proposed inclusion of the risk control requirements of CRD articles 79 through 87, and French implementing provisions, Internal Control Order articles 111, 121 and 130 through 134, within the prerequisites to substituted compliance for internal supervision and control, on the grounds that the inclusion of those provisions ''are not necessary'' to justify substituted compliance.[351] The commenter also recommended deleting the reference to MiFID Org Reg article 23 related to risk management and which the commenter believed was more appropriately addressed with the risk control requirements found in paragraph (b) of the proposed Order.[352] Following the comment period reopening, that commenter further objected to the Commission's suggested inclusion of CRR articles 286–88 and 293 (addressing counterparty credit risk and risk management generally) and EMIR Margin RTS article 2 (addressing

[338] *See id.* at 85727–85728. The condition was designed to allow Covered Entities to use their existing internal supervision and compliance frameworks to comply with the relevant Exchange Act requirements and Order conditions, rather than having to establish separate special-purpose supervision and compliance frameworks.

[339] *See id.* at 85728.

[340] *See id.*

[341] *See* SIFMA Letter at 6–7.

[342] *See* Reopening Release, 86 FR at 18384.

[343] *See id.*

[344] *See* SIFMA Letter II at 18–19 (stating that ''[g]iven that paragraph (d) of the French Order does not extend to the risk management requirements of Exchange Act Section 15F(j)(2) or related requirements of Exchange Act rule 15Fh–3(h), which the French Order instead addresses separately in paragraph (b)(1), we fail to see the justification for adding these requirements to paragraph (d)(3)'').

[345] *Id.* at 19. *See also,* FBF Letter II at 3 (stating that ''the attestation language a bank would need to use when furnishing home country reports is stricter than that required under the SEC rule itself.'')

[346] SIFMA Letter II at 19.

[347] *Id.* at 19–20.

[348] FBF Letter II at 3.

[349] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85740.

[350] *See* SIFMA Letter II at Appendix A. Specifically, SIFMA recommends the deletion of the following conditions from paragraph (d)(3) of the proposed Order: (i) MiFID articles 16(6) through (10); (ii) MiFID Org Reg articles 23, 27, 30 through 32, 72 through 76 and Annex IV; (iii) CRD articles 79 through 87 and 92 through 95; (iv) MFC articles L. 511–71 through 86, L. 511–89 through 97 and L. 511–102; (v) French Internal Control Order articles 111, 121 and 130 through 134; (vi) MFC article R. 511–16–3; and (vii) Prudential Supervision and Risk Assessment Order article 7.

[351] SIFMA Letter I at 6–7.

[352] *See id.* at Appendix A.

collateral-related risk management procedures) to the prerequisites.[353] The commenter argued that those additions inappropriately would ''expand the substantive ambit of the linked Exchange Act requirements.'' [354] The Commission nonetheless concludes that those CRD, CRR, MiFID Org Reg, and EMIR Margin RTS provisions appropriately constitute part of the substituted compliance conditions for internal supervision and compliance. Supervision and compliance requirements serve the purpose of causing registered entities to have systems and follow practices to help ensure they conduct their business as required. It would be paradoxical to conclude that an SBS Entity that fails to implement requisite internal risk management systems and practices nonetheless may be considered to be following supervision and compliance standards that are sufficient to meet the regulatory outcomes required under the Exchange Act. A risk management failure necessarily constitutes a compliance failure. Accordingly, the Commission is retaining the references to these provisions. The commenter also requested the removal of MFC R. 511–16–3, based on the claim that it does not exist.[355] However, the Commission has not determined that to be the case.[356]

One commenter recommended that the Commission delete MiFID article 16(6) through 16(10) related to recordkeeping and client asset safeguarding requirements and the corresponding French implementing provisions; [357] CRD articles 92 through 95, MFC articles L. 511.71 through L. 511.86, and MiFID Org Reg article 27 related to remuneration, MiFID Org Reg articles 30 through 32 related to outsourcing; [358] and MFC articles L. 511–89 through L. 511–97 and L. 511–102 related to risk and remuneration committees. The commenter stated that those provisions ''do not correspond to, and go beyond,'' the applicable requirements of the Exchange Act.[359] In addition, the commenter stated that the MiFID provisions ''did not relate to supervisory or compliance requirements.'' [360] The Commission believes that the MiFID and corresponding French implementing provisions and MiFID Org Reg conditions taken as a whole are relevant to its substituted compliance determination for internal supervision and compliance and taken together the specified French and EU provisions promote adequate supervision within the Covered Entities complying with those requirements. Accordingly, the Commission is retaining the references to these provisions with one exception.[361]

The comparability analysis requires consideration of Exchange Act requirements as a whole against analogous French and EU requirements as a whole, recognizing that U.S. and non-U.S. regimes may follow materially different approaches in terms of specificity and technical content. This ''as a whole'' approach—which the Commission is following in lieu of requiring requirement-by-requirement similarity—further means that the conditions to substituted compliance should encompass all French and EU requirements that establish comparability with the applicable regulatory outcome. It would be inconsistent with the holistic approach to excise relevant requirements and leave only the residual French and EU provisions that most closely resemble the analogous Exchange Act requirements.[362] In reaching this conclusion, the Commission emphasizes the importance of ensuring that substituted compliance is grounded on the comparability of regulatory outcomes.[363]

2. Compliance Report Certifications

Commenters requested that the standard applied to the certification of required compliance reports upon their submission to the Commission be revised to conform more closely with the requirements set forth in Exchange Act rule 15Fk–1.[364] Rule 15Fk–1 states that the required reports must include ''a certification by the chief compliance officer or senior officer that, to the best of his or her knowledge and reasonable belief and under penalty of law, the information contained in the compliance report is accurate and complete in all material respects.'' [365] The standard applied in the proposed Order required certification that ''under penalty of law, the report is accurate and complete.'' [366] The Commission concurs that alignment of the Order's certification requirement with that of the applicable Exchange Act rule is appropriate in this instance. Therefore, the Order has been updated to clarify that the required reports should be certified by ''the chief compliance officer or senior officer'' of the Covered Entity and that the same certification standard contained in Exchange Act rule 15Fk–1 applies.[367] In addition, the Order has been updated to clarify that the certification must cover compliance with applicable Exchange Act requirements, consistent with the requirements regarding internal supervision.[368] The Commission believes that this clarification is necessary, particularly in light of its granular approach to substituted compliance, to ensure that the report covers applicable Exchange Act requirements whether or not the SBS Entity relies on substituted compliance for internal supervision.

3. Timing of Compliance Report Submission

Commenters requested that the Order be amended to clarify the timing for

[353] *See* Reopening Release, 86 FR at 18348 (stating that those provisions ''promote analogous compliance goals'' as the other proposed conditions to substituted compliance for internal supervision and compliance).

[354] SIFMA Letter II at 18–19 (''Simply asserting that these requirements 'promote analogous compliance goals' is not enough; under that theory, seemingly every provision of EU or French law would be relevant to internal supervision and compliance, but this cannot be the case.'').

[355] SIFMA Letter II at Appendix A.

[356] MFC R. 511–16–3 acts as the French implementing provision for CRD article 91(8), which the commenter did not object to including, and both of which were included in the proposed Order and are now included in paragraph (d)(3) of the Order.

[357] MiFID articles 16(6) through 16(10) is implemented in France in MFC articles 1.533–10.II 6 through 9 and L. 533–10.III which are included as conditions to supervisory and compliance substituted compliance in paragraph (d)(3) of the Order.

[358] *See* SIFMA Letter II at Appendix A. Paragraph (d)(3) of the proposed Order also included MiFID Org Reg articles 23 and 72 through 76 and Annex IV as conditions to internal supervision substituted compliance. These MiFID Org Reg articles relate to risk management and recordkeeping, respectively, and are addressed elsewhere in this section.

[359] *See* SIFMA Letter at II Appendix A.

[360] *Id.*

[361] The Commission is deleting the requirements related to CRD article 93 and related implementing provisions, as they were not part of the French Authorities' Application, and relate to remuneration policies for institutions that benefit from exceptional (French and EU) government intervention.

[362] The Commission believes that those conditions to substituted compliance do not ''expand the substantive ambit of the linked Exchange Act requirements'' given that substituted compliance is an option available to non-U.S. SBS Entities—not a mandate.

[363] *See* Better Markets Letter at 3 (addressing need for a ''compelling showing'' of comparability).

[364] *See* SIFMA Letter I at 7 n.14; SIFMA Letter II at 19 (stating that ''paragraph (d)(2)(ii)(B) of the French Order should be conformed to be consistent with the linked Exchange Act requirement.''); *see also* FBF Letter at 3 (stating that ''the attestation language a bank would need to use when furnishing home country reports is stricter than that required under the SEC rule itself.'').

[365] *See* Exchange Act rule 15Fk–1(c)(2)(ii)(D). *See also* Exchange Act rule 15Fk–1(e)(2) (defining ''senior officer'' as ''the chief executive officer or other equivalent officer'').

[366] French Substituted Compliance Notice and Proposed Order, 81 FR at 85740.

[367] *See* para. (d)(2)(ii)(B) of the Order.

[368] *See* para. (d)(4) of the Order.

Covered Entities to submit compliance reports to the Commission, and suggested standards by which ''the Covered Entity may make an annual submission of this report 15 days after submission to the AMF.'' [369] One commenter explained that absent such a clarification, submission of the report seemingly would be required within 30 days following the deadline for the Covered Entity to file its annual financial report with the Commission, without regard to when the entity prepares its report pursuant to MiFID.[370] Another commenter stated that providing a clarified 15 day timeline would accommodate ''the need to account for translation as well as other conditions in the French Order.'' [371]

The Commission is persuaded that additional clarification is warranted, concurs that it is appropriate for the Commission to receive compliance reports shortly after their preparation, and views 15 days as providing a reasonable time to translate and convey reports. At the same time, the Commission does not believe that the suggested ''15 days after submission to the AMF'' standard sets forth an optimal timing condition, in part given that MiFID Org Reg article 22(2)(c) requires reports to the firm management body—not to authorities such as the AMF.

Instead, to promote timely notice comparable to what the Exchange Act rule provides, the Commission is incorporating a timing standard that accounts for MiFID-required timing as well as the possibility that the relevant reports may be submitted to the management body early. Under the Order, the applicable compliance reports are to be provided to the Commission no later than 15 days following the earlier of: (i) The submission of the report to the Covered Entity's management body; or (ii) the time the report is required to be submitted to the management body.[372] In addition, reports required to be provided under MiFID Org Reg article 22(2)(c) must together cover the entire period that an Exchange Act rule 15Fk–1 annual report would have covered. This requirement would prevent a Covered Entity from applying for substituted compliance just prior to the due date of its Exchange Act annual report and then providing the Commission its next MiFID Org Reg report covering only a part of the year that would have been covered in the Exchange Act report.

4. Compliance Reports Subject to Disclosure

One commenter requested that the proposed Order be modified to narrow the scope of the compliance reports provided to the Commission, stating that the conditions to substituted compliance should require that the Commission be provided with the compliance reports only ''to the extent they are related to a Covered Entity's business as an SBS Entity.'' [373] The commenter argued that it would be ''disproportionate and unnecessary'' to require that the Commission receive all reports prepared pursuant to MiFID Org Reg article 22(2)(c).[374]

The Commission disagrees, and believes that the Commission should be fully informed—consistent with the scope of MiFID Org Reg article 22(2)(c)—as to the ''implementation and effectiveness'' of the Covered Entity's ''overall control environment for investment services and activities,'' as well as associated risks, complaints handling and remedies. The alternative approach of apportioning compliance reports into two buckets, and only providing one bucket to the Commission, does not match the analytic approach of considering the Exchange Act and French/EU frameworks ''as a whole.''

5. Compliance Conditions Related to Recordkeeping

The Commission also is not adopting a commenter's suggestion that MiFID Org Reg articles 72 through 76 and Annex IV recordkeeping requirements be removed from the conditions for substituted compliance for internal supervision and compliance.[375] Documentation is an important component of an effective compliance system, and a firm that has failed to comply with relevant EU recordkeeping requirements cannot reasonably be viewed as having engaged in supervisory and compliance practices that are sufficiently rigorous to satisfy the regulatory outcome established by the relevant requirements under the Exchange Act.

6. Additional Considerations and Final Order Provisions

For these reasons, the Commission is adopting the requirements related to internal supervision and compliance largely as proposed, subject to the specific changes addressed above.[376] Consistent with the proposed Order, substituted compliance in connection with internal supervision further is conditioned on the Covered Entity being subject to and complying with the applicable French and EU supervisory and compliance provisions listed in paragraph (d)(3) of the Order, *as if* those provisions also require SBS Entities to comply with applicable requirements under the Exchange Act and the other applicable conditions to the Order.[377] Similarly, substituted compliance in connection with the chief compliance officer requirements further is conditioned on the compliance reports provided to the Commission addressing the SBS Entity's compliance with other applicable conditions of the Order.[378] A Covered Entity that is unable to comply with an applicable condition—and thus is not eligible to use substituted compliance for the Exchange Act internal supervision and/or chief compliance officer requirements related to that condition—nevertheless may use substituted compliance for another set of Exchange Act requirements addressed in the Order if it complies with the conditions to the relevant parts of the Order.

Under the Order, substituted compliance for internal supervision and chief compliance officer requirements is not subject to a condition that the Covered Entity apply substituted compliance for related recordkeeping requirements in Exchange Act rules 18a–5 and 18a–6. A Covered Entity that applies substituted compliance for

[369] *See* SIFMA Letter II at 19–20; *see also* FBF Letter II at 3 (requesting that the report be submitted to the SEC ''15 days after its submission to the AMF in April each year''). With regard to the UK Substituted Compliance Notice and Proposed Order, SIFMA supported a single annual submission for multiple reports without reference to a 15 day timing standard. *See* SIFMA UK Letter at 21.

[370] SIFMA Letter II at 19–20, 31. The ''15 days after submission to the AMF'' language is incorporated into the commenter's ''detailed recommendations'' (at page 31). The commenter's general discussion of the issue separately alludes to a ''15 days after the Covered Entity completes its annual MiFID report as required by MiFID'' standard (at page 20).

[371] FBF Letter II at 3.

[372] *See* para. (d)(2)(ii)(D) of the Order.

[373] SIFMA Letter II at 19.

[374] *Id.*

[375] SIFMA Letter I at 6–7.

[376] *See* para. (d)(3) of the Order. Consistent with the discussion above related to internal risk management (part IV.B.1), the condition has been modified from the proposed Order by removing Prudential Supervision and Risk Assessment Order article 7.

[377] *See* para. (d)(4) of the Order. The Order provides that the Covered Entity must comply with relevant French and EU provisions as if those provisions address applicable conditions of the Order connected to requirements for which the Covered Entity is relying on substituted compliance. That part of the condition does not apply to parts of the Order for which the Covered Entity does not rely on substituted compliance.

[378] *See* para. (d)(2)(ii) of the Order. For the reasons discussed in the proposal, the substituted compliance Order does not extend to antitrust provisions under the Exchange Act.

internal supervision and/or chief compliance officer requirements, but does not apply substituted compliance for the related recordkeeping requirements in Exchange Act rules 18a–5 and 18a–6, will remain subject to the relevant provisions of Exchange Act rules 18a–5 and 18a–6. Those rules require the Covered Entity to make and preserve records of its compliance with Exchange Act internal supervision and chief compliance officer requirements and of its security-based swap activities required or governed by those requirements. A Covered Entity that applies substituted compliance for internal supervision and/or chief compliance officer requirements, but complies directly with related recordkeeping requirements in rules 18a–5 and 18a–6, therefore must make and preserve records of its compliance with the relevant conditions of the Order and of its security-based swap activities required or governed by those conditions and/or referenced in the relevant parts of rules 18a–5 and 18a–6.

Finally, for the reasons discussed in the proposed Order, moreover, the substituted compliance Order does not extend to antitrust provisions under the Exchange Act.[379]

VII. Substituted Compliance for Counterparty Protection Requirements

A. Proposed Approach

The French Authorities' Application in part requested substituted compliance in connection with counterparty protection requirements relating to:

- Disclosure of material risks and characteristics and material incentives or conflicts of interest—Requirements that an SBS Entity disclose to certain security-based swap counterparties certain information about the material risks and characteristics of the security-based swap, as well as material incentives or conflicts of interest that the SBS Entity may have in connection with the security-based swap.
- ''Know your counterparty''—Requirements that an SBS Entity establish, maintain and enforce written policies and procedures to obtain and retain certain information regarding a security-based swap counterparty that is necessary for conducting business with that counterparty.
- Suitability—Requirements for a security-based swap dealer to undertake reasonable diligence to understand the potential risks and rewards of any recommendation of a security-based swap or trading strategy involving a security-based swap that it makes to certain counterparties and to have a reasonable basis to believe that the recommendation is suitable for the counterparty
- Fair and balanced communications—Requirements that an SBS Entity communicate with security-based swap counterparties in a fair and balanced manner based on principles of fair dealing and good faith.
- Daily mark disclosure—Requirements that an SBS Entity provide daily mark information to certain security-based swap counterparties.
- Clearing rights disclosure—Requirements that an SBS Entity provide certain counterparties with information regarding clearing rights under the Exchange Act.

Taken as a whole, these counterparty protection requirements help to ''bring professional standards of conduct to, and increase transparency in, the security-based swap market and to require registered SBS Entities to treat parties to these transactions fairly.''[380]

The proposed Order provided for conditional substituted compliance in connection with fair and balanced communications, disclosure of material risks and characteristics, disclosure of material incentives or conflicts of interest, ''know your counterparty,'' suitability and daily mark disclosure requirements.[381] In proposing to provide conditional substituted compliance for these requirements, the Commission preliminarily concluded that the relevant French and EU requirements in general would produce regulatory outcomes that are comparable to requirements under the Exchange Act, by subjecting French Covered Entities to obligations that promote standards of professional conduct, transparency and the fair treatment of parties.

As proposed, substituted compliance for these requirements would be subject to certain conditions to help ensure the comparability of outcomes. First, under the proposed Order, substituted compliance for fair and balanced communications, disclosure of material risks and characteristics, disclosure of material incentives or conflicts of interest, ''know your counterparty,'' and suitability requirements would be conditioned on Covered Entities being subject to, and complying with, relevant French and EU requirements.[382] Second, the proposed Order would additionally condition substituted compliance for suitability requirements on the counterparty being a ''professional client'' as defined in MiFID (rather than a ''retail client'' or an elective ''professional client'')[383] and not a ''special entity'' as defined in Exchange Act section 15F(h)(2)(C) and Exchange Act rule 15Fh–2(d).[384] Finally, in the proposed Order the Commission preliminarily viewed certain types of EU daily portfolio reconciliation requirements as comparable to Exchange Act daily mark disclosure requirements.[385] These daily portfolio reconciliation requirements apply to portfolios of a financial counterparty or a non-financial counterparty subject to the clearing obligation in EMIR in which counterparties have 500 or more OTC derivatives contracts outstanding with each other.[386] The Commission preliminarily viewed EU portfolio reconciliation requirements for other types of portfolios, which may be reconciled less frequently than each business day or may not require disclosure to counterparties, as not comparable to Exchange Act daily mark requirements.[387] Accordingly, the proposed Order would condition substituted compliance for daily mark requirements on the Covered Entity being required to reconcile, and in fact reconciling, the portfolio containing the relevant security-based swap on each business day and exchanging valuations of those contracts directly between counterparties, pursuant to relevant EU requirements.[388]

The Order would not provide substituted compliance in connection with Exchange Act requirements for SBS Entities to disclose a counterparty's clearing rights under Exchange Act section 3C(g)(5). The French Authorities' Application cited certain

[379] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85728.

[380] *See* Business Conduct Adopting Release, 81 FR at 30065.

[381] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85728–29.

[382] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85729 n.72.

[383] Annex II of MiFID describes which clients are ''professional clients.'' Section I of Annex II describes the types of clients considered to be professional clients unless the client elects non-professional treatment; these clients are per se professional clients. Section II of Annex II describes the types of clients who may be treated as professional clients on request; these clients are elective professional clients. *See* MiFID Annex II. Retail clients are those that are not professional clients. *See* MiFID article 4(1)(11).

[384] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85730.

[385] *Id.* at 85729–85730.

[386] *See* EMIR RTS article 13(3)(a)(i); EMIR article 10.

[387] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85730.

[388] *Id.*

EU provisions related to a counterparty's clearing rights in the European Union. However, those provisions do not require disclosure of Exchange Act section 3C(g)(5) clearing rights, and the Commission preliminarily viewed the EU clearing provisions as not comparable to Exchange Act clearing rights disclosure requirements.[389]

B. Commenter Views and Final Provisions

Having considered the commenter recommendations for the counterparty protection requirements, the Commission is making positive substituted compliance determinations in connection with disclosure of material risks and characteristics, disclosure of material incentives or conflicts of interest, ''know your counterparty,'' suitability, fair and balanced communications and daily mark disclosure requirements. The Order is largely consistent with the proposed Order, except for adding additional EU requirements in two sections of the Order, moving one EU requirement from the fair and balanced communications section of the Order to the disclosure of material incentives and conflicts of interest section and adding text to clarify that substituted compliance for counterparty protection requirements is applied at the transaction level.[390] This action is grounded in the Commission's conclusion that, taken as a whole, applicable requirements under French and EU law subject French Covered Entities to obligations that promote standards of professional conduct, transparency and the fair treatment of parties, and thus produce regulatory outcomes that are comparable to the outcomes associated with the relevant counterparty protection requirements under the Exchange Act.

To help ensure the comparability of outcomes, substituted compliance is subject to certain conditions. Substituted compliance for disclosure of material risks and characteristics,[391] disclosure of material incentives or conflicts of interest,[392] ''know your counterparty'',[393] suitability[394] and fair and balanced communications[395] requirements is conditioned on a Covered Entity being subject to, and complying with, relevant French and EU requirements. Substituted compliance for daily mark disclosure requirements is conditioned on the Covered Entity being required to reconcile, and in fact reconciling, the portfolio containing the relevant security-based swap on each business day pursuant to relevant EU requirements.[396] Substituted compliance for suitability requirements is conditioned on the counterparty being a per se ''professional client'' as defined in MiFID (*i.e.,* not an elective professional client or a retail client) and not a ''special entity'' as defined in Exchange Act section 15F(h)(2)(C) and Exchange Act rule 15Fh–2(d).[397] A Covered Entity that is unable to comply with a condition—and thus is not eligible to use substituted compliance for the particular set of Exchange Act counterparty protection requirements related to that condition—nevertheless may use substituted compliance for another set of Exchange Act requirements addressed in the Order if it complies with the conditions to the relevant parts of the Order.

The Commission recognizes that there are differences between the approaches taken by disclosure of material risks and characteristics, disclosure of material incentives or conflicts of interest, ''know your counterparty,'' suitability, fair and balanced communications and daily mark disclosure requirements under the Exchange Act, on the one hand, and relevant French and EU requirements, on the other hand. The Commission continues to view those differences, when coupled with the conditions described above, as not so material as to be inconsistent with substituted compliance within the requisite outcomes-oriented context. With respect to Exchange Act clearing rights disclosure requirements, however, consistent with the proposed Order the Commission is not providing substituted compliance.

Under the Order, substituted compliance for counterparty protection requirements (relating to disclosure of information regarding material risks and characteristics, disclosure of information regarding material incentives or conflicts of interest, ''know your counterparty,'' suitability, fair and balance communications and daily mark disclosure) is not subject to a condition that the Covered Entity apply substituted compliance for related recordkeeping requirements in Exchange Act rules 18a–5 and 18a–6. A Covered Entity that applies substituted compliance for one or more counterparty protection requirements, but does not apply substituted compliance for the related recordkeeping requirements in Exchange Act rules 18a–5 and 18a–6, will remain subject to the relevant provisions of Exchange Act rules 18a–5 and 18a–6. Those rules require the Covered Entity to make and preserve records of its compliance with Exchange Act counterparty protection requirements and of its security-based swap activities required or governed by those requirements. A Covered Entity that applies substituted compliance for a counterparty protection requirement, but complies directly with related recordkeeping requirements in rules 18a–5 and 18a–6, therefore must make and preserve records of its compliance with the relevant conditions of the Order and of its security-based swap activities required or governed by those conditions and/or referenced in the relevant parts of rules 18a–5 and 18a–6.

One commenter requested that the Commission make several changes to the conditions in the proposed Order.[398] The Commission details its response to each of those requests below.

1. Disclosure of Information Regarding Material Risks and Characteristics

The commenter requested that the Commission not require a Covered Entity to be subject to and comply with MIFID Org Reg articles 49 and 50 and requested that the requirement for a Covered Entity to be subject to and comply with MiFID article 24(4) and MFC D. 533–15 be narrowed to include only MiFID article 24(4)(b) and MFC D. 533–15.2°, respectively.[399] The commenter described the proposed removal of conditions as addressing requirements ''which do not correspond to, and go beyond, the requirements in Exchange Act rule 15Fh–3(b).''[400]

The commenter stated that MiFID Org Reg article 49 relates to information about the safeguarding of client financial instruments or client funds and thus goes beyond the scope of Exchange Act material risks and characteristics disclosure requirements.[401] This provision would require a Covered Entity to inform its client about the risks of the Covered Entity placing client assets, which

[389] *Id.*

[390] *See* para. (e) of the Order.

[391] *See* para. (e)(1) of the Order.

[392] *See* para. (e)(2) of the Order.

[393] *See* para. (e)(3) of the Order.

[394] *See* para. (e)(4)(i) of the Order.

[395] *See* para. (e)(5) of the Order.

[396] Covered Entities must be required to reconcile, and in fact reconcile, the portfolio containing the security-based swap for which substituted compliance is applied, on each business day pursuant to EMIR articles 11(1)(b) and 11(2) and EMIR RTS article 13. *See* para. (e)(6) of the Order.

[397] *See* para. (e)(4)(ii) of the Order.

[398] *See* SIFMA Letter II at Appendix A.

[399] *Id.*

[400] *Id.*

[401] *Id.*

would include the relevant security-based swap and funds related to it, to be held by a third party, the risks of the Covered Entity holding client assets in an omnibus account, the risks of holding client assets that are not segregated from the assets of the Covered Entity or a third party holding the client's assets and the risks of the Covered Entity entering into securities financing transactions using client assets. A Covered Entity also would have to inform the client when the relevant security-based swap is held in an account subject to the laws of a jurisdiction other than France and indicate that client rights relating to the security-based swap may differ from those under French law. A Covered Entity also would have to inform the client about any security interest, lien or right of set-off that the Covered Entity or a depository may have over client assets. In comparison, Exchange Act rule 15Fh–3(b)(1) requires a Covered Entity, before entering into a security-based swap, to disclose to certain counterparties material information about the security-based swap in a manner reasonably designed to allow the counterparty to assess the material risks and characteristics of the security-based swap, which may include market, credit, liquidity, foreign currency, legal, operational and any other applicable risks of the security-based swap. Legal and operational risks of a security-based swap include the types of risks to client assets that MiFID Org Reg article 49 would require the Covered Entity to disclose. Accordingly, the Commission is retaining the references to these provisions.

The commenter stated that MiFID Org Reg 50 relates to the disclosure of costs and charges and thus goes beyond the scope of Exchange Act material risks and characteristics disclosure requirements.[402] Exchange Act rule 15Fh–3(b)(1) requires a Covered Entity, before entering into a security-based swap, to disclose to certain counterparties material information about the security-based swap in a manner reasonably designed to allow the counterparty to assess the material risks and characteristics of the security-based swap, which may include the material economic terms of the security-based swap and the rights and obligations of the parties during the term of the security-based swap. The material economic terms of a security-based swap and the rights and obligations of the parties include the costs and charges associated with the security-based swap. Accordingly, the Commission is retaining the references to these provisions.

Additionally, the commenter requested that MiFID article 24(4) and MFC D. 533–15 be narrowed to only require compliance with MiFID article 24(4)(b) and MFC D. 533–15.2°, because the parts proposed for removal ''relate[ ] to whether the advice is provided on an independent basis and . . . to costs and charges.'' [403] As noted above, Exchange Act rule 15Fh–3(b)(1) requires a Covered Entity, before entering into a security-based swap, to disclose to certain counterparties material information about the security-based swap in a manner reasonably designed to allow the counterparty to assess the material risks and characteristics of the security-based swap, which may include the material economic terms of the security-based swap and the rights and obligations of the parties during the term of the security-based swap. The Commission believes that a counterparty would consider the independence of the Covered Entity in the counterparty's assessment of these risks and characteristics. The Commission addressed the provisions related to costs and charges above. The holistic approach taken by the Commission in considering whether regulatory requirements are comparable further warrants the inclusion of these provisions in the Order. Accordingly, the Commission is retaining the references to these provisions.

2. Disclosure of Information Regarding Material Incentives or Conflicts of Interest

The commenter requested that the Commission not require a Covered Entity to be subject to and comply with MiFID article 24(9) and MFC L. 533–12–4.[404] The commenter stated that these provisions relate to third-party payments and thus go beyond the scope of Exchange Act material incentives or conflicts of interest disclosure requirements. These provisions would require a Covered Entity to refrain from paying to, or accepting from, third parties certain fees, commissions or non-monetary benefits in connection with providing an investment service (inducements) and, in circumstances in which the general prohibition on inducements does not apply, to disclose to the client the existence, nature and amount of the inducement prior to providing the service and in a manner that is comprehensive, accurate and understandable. In comparison, Exchange Act rule 15Fh–3(b)(2) requires a Covered Entity, before entering into a security-based swap, to disclose to certain counterparties material information about the security-based swap in a manner reasonably designed to allow the counterparty to assess the material incentives or conflicts of interest that the Covered Entity may have in connection with the security-based swap, including any compensation or other incentives from any source other than the counterparty. Disclosure of this compensation or other incentives would include disclosure of the existence, nature and amount of an inducement that MiFID article 24(9) and MFC L. 533–12–4 would require the Covered Entity to disclose. Accordingly, the Commission is retaining the references to these provisions.

The Commission is issuing the disclosure of information regarding material incentives or conflicts of interest section of the Order largely as proposed, with the inclusion of two additional EU requirements.[405] MAR Investment Recommendations Regulation articles 5 and 6 enumerate specific obligations in relation to disclosure of interests or of conflicts of interest. Article 5 requires that persons who produce recommendations disclose in their recommendations all relationships and circumstances that may reasonably be expected to impair the objectivity of the recommendation, including interests or conflicts of interest. Article 6 imposes additional obligations on certain entities, including the disclosure of information on their interests and conflicts of interest concerning the issuer to which a recommendation relates. The Commission believes that requiring Covered Entities to be subject to and comply with MAR Investment Recommendations Regulation articles 5 and 6 contributes to a determination that relevant French and EU requirements produce regulatory outcomes that are comparable to relevant requirements of Exchange Act rule 15Fh–3(b). Accordingly, the Commission is adding these two requirements to the Order's list of French and EU disclosure of information regarding material incentives or conflicts of interest requirements that the Covered Entity must be subject to and comply with.[406]

3. ''Know your counterparty''

The commenter requested that the Commission not require a Covered Entity to be subject to and comply with a series of French and EU ''know your

[402] *Id.*

[403] *Id.*

[404] *Id.*

[405] *See* para. (e)(2) of the Order.

[406] *See id.*

counterparty'' requirements specified in the proposed Order, including: MiFID article 16(2); MFC L. 533–10.II(2); MiFID Org Reg articles 21 and 22, 25 and 26 and applicable parts of Annex I; CRD articles 74(1) and 85(1); MFC L. 511–55 and L. 511–41–1–B; MLD articles 11 and 13; L. 561–6, L. 561–10, L. 561–4–1, R. 561–5–2, R. 561–7, R. 561–10–3, R. 561–11–1; MLD articles 8(3) and 8(4)(a) as applied to internal policies, controls and procedures regarding recordkeeping of customer due diligence activities; and MFC L. 561–4–1 as applied to vigilance measures regarding recordkeeping of customer due diligence activities.[407] The commenter also proposed the addition of MFC article L. 561–12 to the Order's ''know your counterparty'' conditions. Similar to other elements of the counterparty protection requirements, the commenter asserted that the conditions identified for removal ''do not correspond to, and go beyond, the requirements of Exchange Act rule 15Fh–3(e).'' [408] However, the commenter's reasons for this overarching claim are unconvincing.

The commenter describes MiFID article 16(2) and MFC L. 533–10.II(2) as relating to ''broad organizational requirements'' without explaining how such characteristics preclude their inclusion when considering whether regulatory requirements are comparable for purposes of substituted compliance.[409] MiFID article 16(2) requires a Covered Entity to establish, implement and maintain adequate policies and procedures sufficient to ensure the Covered Entity's compliance with its obligations under French financial services laws. This requirement relates to the requirement in Exchange Act rule 15Fh–3(e)(1) and (2) for the Covered Entity to establish, maintain and enforce written policies and procedures to obtain and retain a record of the essential facts about the counterparty that are necessary for complying with applicable laws, regulations and rules and for implementing the Covered Entity's credit and operational risk management policies. Accordingly, the Commission is retaining the references to these provisions.

The commenter similarly describes the other conditions proposed for removal, including the MiFID Org Reg articles as ''organizational requirements, compliance, responsibility of senior management, complaints handling and associated recordkeeping.'' [410] However, MiFID Org Reg articles 21, 22, 25, 26 and applicable parts of Annex I are regulations that implement MiFID article 16(2). They provide additional detail about the Covered Firm's required policies and procedures under the French regulatory framework, and as such are relevant to the policies and procedures required under Exchange Act rule 15Fh–3(e). Accordingly, the Commission is retaining the references to these provisions.

The commenter states that CRD articles 74(1) and 85(1), and MFC L. 511–55 and L. 511–41–1–B are ''governance and prudential requirements,'' and thus go beyond the scope of Exchange Act ''know your counterparty'' requirements.[411] CRD article 74(1) would require the Covered Entity to have robust governance arrangements, including effective processes to identify, manage, monitor and report the risks it is or might be exposed to. CRD article 85(1) would require the Covered Entity to implement policies and processes to evaluate and manage the exposures to operational risk. These requirements relate to the requirement in Exchange Act rule 15Fh–3(e)(2) for the Covered Entity to establish, maintain and enforce written policies and procedures to obtain and retain a record of the essential facts about the counterparty that are necessary for implementing the Covered Entity's credit and operational risk management policies. Accordingly, the Commission is retaining the references to these provisions.

The commenter states that MLD articles 8(3), 8(4)(a), 11 and 13, are simply ''overbroad,'' and therefore ''do not correspond to, and go beyond, the requirements of Exchange Act rule 15Fh–3(e).'' [412] Similarly, the commenter states that MFC articles L. 561–6, L. 561–10, R. 561–5–2, R. 561–7, R. 561–10–3 and R. 561–11–1, which in part implement MLD articles 11 and 13, and MFC article L. 561–4–1, which implements MLD articles 8(3) and 8(4)(a), are related to ''AML requirements other than KYC'' and that ''it is not appropriate for the Commission effectively to expand the scope and content of its requirements.'' [413] MLD articles 11 and 13, and the corresponding provisions of the MFC, require obliged entities such as a Covered Entity to apply customer due diligence measures at defined points of a business relationship. Those customer due diligence measures include verifying that any person purporting to act on behalf of a customer is so authorized. The customer due diligence measures required by MLD articles 11 and 13 and the corresponding provisions of the MFC thus are directly related to the requirement in Exchange Act 15Fh–3(e)(3) for a Covered Entity to establish, maintain and enforce written policies and procedures to obtain and retain a record of the essential facts about the authority of any person acting for a counterparty. MLD articles 8(3) and 8(4)(a) and MFC article L. 561–4–1 would require a Covered Entity to have in place policies, controls and procedures to mitigate and manage effectively the risks of money laundering and terrorist financing. These policies and processes are related to the requirement in Exchange Act rule 15Fh–3(e)(1) and (2) for the Covered Entity to establish, maintain and enforce written policies and procedures to obtain and retain a record of the essential facts about the counterparty that are necessary for complying with applicable laws, regulations and rules and for implementing the Covered Entity's credit and operational risk management policies. Accordingly, the Commission is retaining the references to these provisions.

The commenter provided no rationale for the proposed inclusion of MFC L. 561–12. Accordingly, the Commission is not adding this provision to the Order.

4. Suitability

The commenter requested that the Commission not require a Covered Entity to be subject to and comply with some of the French and EU suitability requirements specified in the proposed Order, including: MiFID articles 24(3) and 25(1); MFC L. 533–24, L. 533–12(I), and L. 533–12–6; and MiFID Org Reg articles 21(1)(b) and (d). The commenter stated that each of these recommended deletions, ''do not correspond to, and go beyond, the requirements in Exchange Act rule 15Fh–3(f).'' [414] The commenter stated that MiFID article 24(3) and MFC article L. 533–12(I) ''relate to the requirement that any information communicated to clients is fair, clear and not misleading''; that MiFID article 25(1), MFC article L. 533–12–6, and MiFID Org Reg article 21(1)(d) ''refer to the skills, knowledge and expertise of the firm's personnel''; that MFC article L. 533–24 ''relates to obligations imposed on firms who design financial instruments''; and that MiFID Org Reg article 21(1)(b) requires ''that relevant

[407] SIFMA Letter II at Appendix A.

[408] *Id.*

[409] *Id.*

[410] *Id.*

[411] *Id.*

[412] *Id.*

[413] *Id.*

[414] *Id.*

persons are aware of the procedures which must be followed for the proper discharge of their responsibilities.'' [415]

Exchange Act rule 15Fh–3(f) requires an SBS Entity, when making certain security-based swap recommendations to a counterparty, to undertake reasonable diligence to understand the potential risks and rewards associated with the recommendation (the reasonable basis suitability standard) and to have a reasonable basis to believe that the recommendation is suitable for the counterparty (the counterparty-specific suitability standard).[416] MiFID article 25(1) and MFC article L. 533–12–6 would require a Covered Entity to ensure that individuals making personal recommendations to clients in relation to a relevant security-based swap have the necessary knowledge and competence so as to ensure that the Covered Entity is able to meet its obligations under MiFID articles 24 and 25 and the related provisions of the MiFID Org Reg. MiFID article 25(2) and MFC article L. 533–13(I) would require the Covered Entity to obtain information about a client necessary to ensure that it makes only recommendations that are suitable for the client, and thus are relevant to the Exchange Act counterparty-specific suitability standard. Thus, MiFID article 25(1) and MFC article L. 533–12–6 would require the Covered Entity to ensure that recommendations to clients are made with the knowledge and competence necessary to fulfill the Covered Entity's obligation under MiFID article 25(1) and MFC article L. 533–12–6 to make only suitable recommendations. This knowledge and competence requirement in MiFID article 25(1) and MFC article L. 533–12–6 is directly related to the Exchange Act reasonable basis standard.

Moreover, MiFID article 24(3) and MFC Article L. 533–12(I), are particularly relevant to the Exchange Act reasonable basis standard. MiFID article 24(3), together with MiFID article 25(1), would require the Covered Entity to ensure that individuals making recommendations have the knowledge and competence to communicate about the relevant security-based swap in a way that is fair, clear and not misleading. The Commission believes that in order to meet the French requirement to communicate in a fair, clear, and not misleading manner, the Covered Entity's due diligence would reflect that individuals engaged in such communication understand the potential risks and rewards of the recommendation in a manner that is comparable to the requirement in Exchange Act rule 15Fh–3(f)(1)(i). MiFID Org Reg article 21(1)(b) and (d), in turn, would require the Covered Entity to ensure that its personnel have the skills, knowledge and expertise, and be aware of the procedures, necessary to properly discharge their responsibilities, which include their suitability obligations. These requirements again relate to the Exchange Act reasonable basis standard because they would require the Covered Entity to ensure that personnel making recommendations are equipped with the requisite training and information to be able to properly communicate about the relevant security-based swap in a way that complies with its French and EU communication and suitability obligations. For these reasons, the Commission is retaining in the Order the references to the French and EU requirements that the commenter asked to delete.[417]

Additionally, the commenter requested that the Commission change the condition to substituted compliance for Exchange Act suitability requirements that would require the Covered Entity's counterparty to be a ''professional client'' mentioned in MiFID Annex II section I and MFC article D. 533–11.[418] Professional clients mentioned in MiFID Annex II section I and MFC article D. 533–11 are per se professional clients, a category of clients that generally includes those with more experience, knowledge, expertise and resources and that excludes elective professional clients and retail clients. The commenter requested that the Commission expand the condition's definition of ''professional client'' to include elective professional clients mentioned in MiFID Annex II section II and MFC article D. 533–12.[419] Elective professional clients generally have less experience, knowledge, expertise and/or resources than per se professional clients.[420] Because French and EU suitability requirements permit a Covered Entity, when conducting a suitability analysis for elective professional clients, to make certain assumptions,[421] while the Exchange Act permits a similar mechanism only for institutional counterparties, the Commission believes that French and EU suitability requirements are comparable only with respect to per se professional clients.[422] Accordingly, the Commission is retaining the condition requiring the Covered Entity's counterparty to be a per se professional client and is not expanding that condition to permit Covered Entities to apply substituted compliance for Exchange Act suitability requirements when its counterparty is an elective professional client.

5. Fair and Balanced Communications

The Commission is issuing the fair and balanced communications section of the Order largely as proposed, except for two changes.[423] First, the Commission believes that French and EU fair and balanced communications requirements are more comparable to Exchange Act requirements when considering three additional EU requirements: MAR article 20(1) would require the Covered Entity to present recommendations in a manner that ensures the information is objectively presented and to disclose interests and conflicts of interest concerning the financial instruments to which the information relates. MAR Investment Recommendations Regulation article 3 would require a Covered Entity to communicate only recommendations that present facts in a way that they are clearly distinguished from interpretations, estimates, opinions and other types of non-factual information; label clearly and prominently projections, forecasts and price targets; indicate the relevant material assumptions and substantial material sources of information; and include only reliable information or a clear indication when there is doubt about reliability. MAR Investment Recommendations Regulation article 4 would require the Covered Entity to provide in its recommendation additional information about the factual basis of its recommendation. Accordingly, the Commission is adding these three requirements to the Order's list of French and EU fair and balanced communications requirements that the Covered Entity must be subject to and comply with.[424] Second, the proposed Order would have required the Covered Entity to be subject to and comply with MAR Investment Recommendations Regulation article 5,[425] which relates to obligations to disclose conflicts of interest. As discussed above, the Commission is requiring Covered

[415] *Id.*

[416] *See* Exchange Act rule 15Fh–3(f)(1).

[417] *See* para. (e)(4)(i) of the Order.

[418] SIFMA Letter II at Appendix A.

[419] *Id.*

[420] *See* MiFID Annex II section II.1. (stating that elective professional clients ''shall not, however, be presumed to possess market knowledge and experience comparable to that of the categories listed in Section I.'').

[421] *See, e.g.,* MiFID Org Reg article 54(3).

[422] *See* para. (e)(4) of the Order.

[423] *See* para. (e)(5) of the Order.

[424] *See* para. (e)(5) of the Order.

[425] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85741.

Entities to comply with this requirement and with MAR Investment Recommendations Regulation article 6 when using substituted compliance for disclosure of material incentives and conflicts of interest requirements. Accordingly, the Commission believes that MAR Investment Recommendations Regulation article 5 is less relevant to comparability of fair and balanced communications requirements and is deleting the reference to it in relation to substituted compliance for fair and balanced communications.

The Commission did not receive comments on the fair and balanced communications requirements of the counterparty protection section of the proposed Order.

6. Daily Mark Disclosure

A commenter requested that the Commission not require a Covered Entity to be subject to and comply with EMIR article 11(2), stating that it ''is not related to portfolio reconciliation'', but, rather, ''concerns the daily mark-to-market or mark-to-model of contracts.'' [426] The commenter is correct that EMIR article 11(2) would require the Covered Entity to mark-to-market or mark-to-model its non-centrally cleared contracts. Other French portfolio reconciliation requirements contemplate that counterparties will use this valuation as an input to the reconciliation process. For example, a portfolio reconciliation must include at least the valuation attributed to each contract in accordance with EMIR article 11(2).[427] As EMIR article 11(2) sets the standards under which a Covered Entity must calculate this key input in the portfolio reconciliation process, the Commission has determined that this provision is related to portfolio reconciliation and accordingly is retaining the Order's reference to it.[428]

7. Clearing Rights Disclosure

In the proposed Order, the Commission preliminarily determined that French and EU requirements are not comparable to Exchange Act clearing rights disclosure requirements and proposed not to make a positive substituted compliance determination with respect to those requirements.[429] Because French and EU clearing provisions do not require disclosure of a counterparty's clearing rights under Exchange Act section 3C(g)(5), the Commission views those provisions as not comparable to Exchange Act clearing rights disclosure requirements. Commenters did not address this conclusion and, consistent with the proposed Order, the Commission is not providing substituted compliance.

8. Clarifications Related to Conditions

A commenter asked the Commission to revise the Order to follow the approach in the UK Proposed Order, in which the Commission clarified that a Covered Entity may apply substituted compliance for Exchange Act rule 15Fh–3(f)'s suitability requirements to ''one or more recommendations of a security-based swap or trading strategy involving a security-based swap'' subject to those Exchange Act suitability requirements.[430] The commenter proposed adding this same text to the Order.[431] The UK Proposed Order contains similar text with respect to substituted compliance for the other counterparty protection requirements.

Because the counterparty protection requirements are transaction-level requirements, a Covered Entity may decide to apply substituted compliance for those requirements to some of its security-based swap business and decide to comply directly with the Exchange Act (or to comply with another suitable substituted compliance order) for other parts of its security-based swap business. The Commission agrees that the commenter's requested change would help to clarify that substituted compliance for suitability is available for one or more of a Covered Entity's recommendations and also believes that similar changes to the other counterparty protection sections of the Order, consistent with the UK Proposed Order, would clarify those sections of the Order as well. Accordingly, the Commission is modifying each paragraph of the counterparty protection section of the Order to clarify that substituted compliance for counterparty protection requirements is available for one or more of a Covered Entity's relevant activities.[432]

VIII. Substituted Compliance for Recordkeeping, Reporting, Notification, and Securities Count Requirements

A. Proposed Approach

The French Authorities' Application in part requested substituted compliance for requirements applicable to SBS Entities under the Exchange Act relating to:

- *Record Making*—Exchange Act rule 18a–5 requires prescribed records to be made and kept current.[433]
- *Record Preservation*—Exchange Act rule 18a–6 requires preservation of records.[434]
- *Reporting*—Exchange Act rule 18a–7 requires certain reports.[435]
- *Notification*—Exchange Act rule 18a–8 requires notification to the Commission when certain financial or operational problems occur.[436]
- *Securities Count*—Exchange Act rule 18a–9 requires non-prudentially regulated security-based swap dealers to perform a quarterly securities count.[437]
- *Daily Trading Records.* Exchange Act section 15F(g) requires SBS Entities to maintain daily trading records.[438]

Taken as a whole, the recordkeeping, reporting, notification, and securities count requirements that apply to SBS Entities are designed to promote the prudent operation of the firm's security-based swap activities, assist the Commission in conducting compliance examinations of those activities, and alert the Commission to potential financial or operational problems that could impact the firm and its customers.[439]

[426] SIFMA Letter II at Appendix A.

[427] *See* EMIR RTS article 13(2).

[428] *See* para. (e)(6) of the Order.

[429] French Substituted Compliance Notice and Proposed Order, 81 FR at 85730.

[430] SIFMA Letter II at Appendix A.

[431] *Id.*

[432] *See* paras. (e)(1) through (6) of the Order.

[433] *See* 17 CFR 240.18a–5. The French Authorities' Application discusses EU and French requirements that address firms' record creation obligations related to matters such as financial condition, operations, transactions, counterparties and their property, personnel and business conduct. *See* French Authorities' Application Annex I category 2 at 2–42.

[434] *See* 17 CFR 240.18a–6. The French Authorities' Application discusses EU and French requirements that address firms' record preservation obligations related to records that firms are required to create, as well as additional records such as records of communications. *See* French Authorities' Application Annex I category 2 at 43–81.

[435] *See* 17 CFR 240.18a–7. The French Authorities' Application discusses EU and French requirements that address firms' obligations to make certain reports. *See* French Authorities' Application Annex I category 2 at 82–95, 98–104.

[436] *See* 17 CFR 240.18a–8. The French Authorities' Application discusses EU and French requirements that address firms' obligations to make certain notifications. *See* French Authorities' Application Annex I category 2 at 95–98.

[437] *See* 17 CFR 240.18a–9. The French Authorities' Application discusses EU and French requirements that address firms' obligations to perform securities counts. *See* French Authorities' Application Annex I category 2 at 32–38.

[438] *See* 15 U.S.C. 78*o*–10(g). The French Authorities' Application discusses EU and French requirements that address firms' record preservation obligations related to records that firms are required to create, as well as additional records such as records of communications. *See* French Authorities' Application Annex I category 2 at 43–81.

[439] Rule 3a71–6 sets forth additional analytic considerations in connection with substituted compliance for the Commission's recordkeeping, reporting, notification, and securities count requirements. In particular, Exchange Act rule 3a71–6(d)(6) provides that the Commission intends

In proposing to provide conditional substituted compliance in connection with this part of the French Authorities' Application, the Commission preliminarily concluded that the relevant EU and French requirements, subject to conditions and limitations, would produce regulatory outcomes that are comparable to the outcomes associated with the vast majority of the recordkeeping, reporting, notification, and securities count requirements under the Exchange Act applicable to SBS Entities pursuant to Exchange Act rules 18a–5, 18a–6, 18a–7, 18a–8, and 18a–9 and Exchange Act section 15F(g) (collectively, the ''Exchange Act Recordkeeping and Reporting Requirements'').[440]

In the Reopening Release, the Commission sought comment on whether the structure of the substituted compliance determinations with respect to Exchange Act rules 18a–5, 18a–6, 18a–7, 18a–8, and 18a–9 as well as Exchange Act Section 15F(g) should permit a covered entity to apply substituted compliance with respect to certain of these rules (*e.g.,* Exchange Act rules 18a–5 and 18a–6) and comply with the Exchange Act requirements of the remaining rules and statute (*i.e.,* Exchange Act rules 18a–7, 18a–8, and 18a–9, as well as Exchange Act Section 15F(g)).[441] Moreover, the Commission sought comment on whether the structure of the substituted compliance determinations with respect to the recordkeeping rules should provide Covered Entities with greater flexibility to select distinct requirements within the broader rules for which they want to apply substituted compliance.[442]

B. Commenter Views and Final Provisions

1. General Considerations

The Commission received comments addressing the proposed conditional substituted compliance determinations for the Exchange Act Recordkeeping and Reporting Requirements, including with respect to the potential approaches for which comment was sought in the Reopening Release.[443] The comments and the Commission's response to them are discussed below.

The Commission received comment requesting the elimination of references to EU or French requirements that do not apply to third-country branches or that apply to multiple countries' branches of an SBS Entity.[444] The same commenter suggested as another possible solution that SBS Entities be permitted to elect to comply directly with U.S. law instead of EU or French requirements.[445] Accordingly, in the Reopening Release, the Commission solicited comment on whether to structure its preliminary substituted compliance determinations for Exchange Act rules 18a–5, 18a–6, 18a–7, and 18a–8 to provide Covered Entities with greater flexibility to select which distinct requirements within the broader rules for which they want to apply substituted compliance.[446] This flexibility was intended to permit Covered Entities to leverage existing recordkeeping and reporting systems that are designed to comply with the broker-dealer recordkeeping and reporting requirements on which the recordkeeping and reporting requirements applicable to SBS Entities are based. For example, it may be more efficient for a Covered Entity to comply with certain Exchange Act requirements within a given recordkeeping or reporting rule (rather than apply substituted compliance) because it can utilize systems that its affiliated broker-dealer has implemented to comply with them.

As applied to Exchange Act rules 18a–5 and 18a–6, this approach of providing greater flexibility resulted in preliminary substituted compliance determinations with respect to the different categories of records these rules require SBS Entities to make, keep current, and/or preserve. The objectives of these rules—taken as a whole—is to assist the Commission in monitoring and examining for compliance with Exchange Act requirements applicable to SBS Entities as well as to promote the prudent operation of these firms.[447] The Commission preliminarily found that the comparable EU and French recordkeeping rules achieve these outcomes with respect to compliance with EU and French requirements for which positive substituted compliance determinations were made (*e.g.,* capital and margin requirements). At the same time, the recordkeeping rules address different categories of records through distinct requirements within the rules. Each requirement with respect to a specific category of records (*e.g.,* paragraph (a)(2) of Exchange Act rule 18a–5 addressing ledgers (or other records) reflecting all assets and liabilities, income and expense and capital accounts) can be viewed in isolation as a distinct recordkeeping rule. Therefore, the Commission solicited comment on whether it would be appropriate to make substituted compliance determinations at this level of Exchange Act rules 18a–5 and 18a–6.[448]

A commenter generally supported the Commission's proposed granular approach to making substituted compliance determinations.[449] The Order takes this granular approach.

The Commission's substituted compliance determinations for the Exchange Act Recordkeeping and Reporting Requirements were subject to the condition that the Covered Entity is subject to and complies with the relevant EU and French laws.[450] Further, the Commission proposed or solicited comment on limitations and additional conditions for certain of the proposed substituted compliance determinations. The limitations and conditions are discussed below as well any comments on them and the Commission's response to those comments.

First, the Commission solicited comment on not making a positive substituted compliance determination with respect to a discrete provision of the Exchange Act Recordkeeping and Reporting Requirements if it was fully or partially linked to a substantive Exchange Act requirement for which substituted compliance was not available or for which a positive substituted compliance determination was not being made.[451] The

to consider (in addition to any conditions imposed) ''whether the foreign financial regulatory system's required records and reports, the timeframes for recording or reporting information, the accounting standards governing the records and reports, and the required format of the records and reports'' are comparable to applicable provisions under the Exchange Act, and whether the foreign provisions ''would permit the Commission to examine and inspect regulated firms' compliance with the applicable securities laws.''

[440] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85731–34.

[441] *See* Reopening Release, 86 FR at 18347–48.

[442] *Id.* The Commission directed commenters to the UK Substituted Compliance Notice and Proposed Order to indicate how the approaches discussed above would be implemented in ordering language. *See also* UK Substituted Compliance Notice and Proposed Order, 86 FR at 18394–404, 18415–20.

[443] *See* SIFMA Letter II at 17–18 and Appendix A.

[444] *See* SIFMA Letter I at 2–4.

[445] *See* SIFMA Letter I at 8–9.

[446] *See* Reopening Release, 86 FR at 18347–48.

[447] *See, e.g.,* Exchange Act Release No. 71958 (Apr. 17, 2014), 79 FR 25194, 25199–200 (May 2, 2014).

[448] *See* Reopening Release, 86 FR 18347. The Commission directed commenters to the UK Substituted Compliance Notice and Proposed Order to indicate how this approach would be implemented in ordering language. *See also* UK Substituted Compliance Notice and Proposed Order, 86 FR at 18396–404, 18415–18.

[449] *See* SIFMA Letter II at 17–18.

[450] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85731–34; Reopening Release, 86 FR at 18347–48.

[451] *See* Reopening Release, 86 FR at 18347–48 (discussing this limitation). The Commission

Continued

Commission linked a requirement in Exchange Act rule 18a–5 to Exchange Act rule 10b–10. A commenter pointed out that Covered Entities will not be subject to Exchange Act rule 10b–10.[452] The Commission agrees with the commenter that there are no provisions in the Exchange Act Recordkeeping and Reporting Requirements that are linked to Exchange Act rule 10b–10. Consequently, the Order does not contain this exclusion.

Aside from this modification, the Order does not extend substituted compliance to discrete Exchange Act Recordkeeping and Reporting Requirements that are linked to substantive Exchange Act requirements for which there is no substituted compliance. In particular, a positive substituted compliance determination is not being made, in full or in part, for recordkeeping, reporting, or notification requirements linked to the following Exchange Act rules for which substituted compliance is not available or a positive substituted compliance determination is not being made: (1) Exchange Act rule 15Fh–4; (2) Exchange Act rule 15Fh–5; (3) Exchange Act rule 15Fh–6; (4) Exchange Act rule 18a–2; (5) Exchange Act rule 18a–4; Exchange Act rule 18a–7(i); and (6) Regulation SBSR.

In addition, Exchange Act rule 18a–6(c) in part requires firms to preserve Forms SBSE, SBSE–A, SBSE–C, SBSE–W, all amendments to these forms, and all other licenses or other documentation showing the firm's registration with any securities regulatory authority or the U.S. Commodity Futures Trading Commission. Because these requirements are linked to the Commission's and other U.S. regulators' registration rules, for which substituted compliance is not available, the Order excludes the requirement to preserve these records from the Commission's positive substituted compliance determination with respect to Exchange Act rule 18a–6(c).[453]

Second, the Commission did not make a positive substituted compliance determination with respect to the inspection requirement of Exchange Act section 15F(f) and the records production the requirement of Exchange Act rule 18a–6(g).[454] The Commission did not receive comment on this approach and the Order does not extend substituted compliance to these requirements.

Third, the Commission solicited comment on conditioning substituted compliance with discrete provisions of the Exchange Act Recordkeeping and Reporting Requirements that were fully or partially linked to a substantive Exchange Act requirement for which substituted compliance was available on the Covered Entity applying substituted compliance with respect to the linked Exchange Act requirement.[455] In particular, substituted compliance for a provision of the Exchange Act Recordkeeping and Reporting Requirements that is linked to the following Exchange Act rules is conditioned on the SBS Entity applying substituted compliance to the linked substantive Exchange Act rule: (1) Exchange Act rule 15Fh–3; (2) Exchange Act rule 15Fi–2; (3) Exchange Act rule 15Fi–3; (4) Exchange Act rule 15Fi–4; (5) Exchange Act rule 15Fi–5; (6) Exchange Act rule 15Fk–1; (7) Exchange Act rule 18a–1 (''Rule 18a–1 Condition''); (8) Exchange Act rule 18a–3; (8) Exchange Act rule 18a–5; and (9) Exchange Act rule 18a–7. The Commission did not receive comment on this approach and is adopting it in the Order. The only difference is that the positive substituted compliance determination for Exchange Act rule 18a 6(b)(1)(viii) is now conditioned on the Covered Entity applying substituted compliance for the requirements of Exchange Act rule 18a–7(a)(1), (b), (c) through (h), and Exchange Act rule 18a–7(j) as applied to these requirements, rather than on the entirety of Exchange Act rule 18a–7, to reflect that substituted compliance with respect to Exchange Act rule 18a–7 is granted on a paragraph-by-paragraph basis and not all paragraphs of Exchange Act rule 18a–7 are pertinent to Exchange Act rule 18a–6(b)(1)(viii).

Moreover, for the reasons discussed above in part III.B.2.e. of this release, substituted compliance with respect to paragraphs (a)(1), (b), and (c) through (h) of Exchange Act rule 18a–7 is subject to the additional condition that the Covered Entity applies substituted compliance with respect to Exchange Act rule 18a–6(b)(1)(viii) (a record preservation requirement).[456] This record preservation requirement is directly linked to the financial and operational reporting requirements of paragraphs (a)(1), (b), and (c) through (h) of Exchange Act rule 18a–7. The UK Proposed Order conditioned substituted compliance with respect to this record preservation requirement on the Covered Entity applying substituted compliance with respect to Exchange Act rule 18a–7(a)(1).[457] This additional condition is designed to provide clarity as to the Covered Entity's obligations under this record preservation requirement when applying substituted compliance with respect to paragraphs (a)(1), (b), and (c) through (h) of Exchange Act rule 18a–7 pursuant this Order.

Fourth, the Commission conditioned substituted compliance with discrete provisions of the Exchange Act Recordkeeping and Reporting Requirements that would be important for monitoring or examining compliance with the capital rule for nonbank security-based swap dealers on the Covered Entity applying substituted compliance with respect to the capital rule (*i.e.,* the Rule 18a–1 Condition).[458] The Commission did not receive comment on this aspect of the Reopening Release and the Order includes the Rule 18a–1 condition for discrete provisions of the Exchange Act Recordkeeping and Reporting Requirements that would be important for monitoring or examining compliance with the capital rule for nonbank security-based swap dealers, as proposed.[459]

directed commenters to the UK Substituted Compliance Notice and Proposed Order to indicate how this approach would be implemented in ordering language. *See also* UK Substituted Compliance Notice and Proposed Order, 86 FR at 18395, 18415–20.

[452] *See* SIFMA Letter II at 18.

[453] *See* para. (f)(2)(i)(L) of the Order.

[454] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85734 (discussing this condition).

[455] *See* Reopening Release, 86 FR at 18348 (discussing this condition). The Commission directed commenters to the UK Substituted Compliance Notice and Proposed Order to indicate how this approach would be implemented in ordering language. *See also* UK Substituted Compliance Notice and Proposed Order, 86 FR 18395, 18415–20.

[456] *See* para. (f)(3)(i)(D) of the Order.

[457] *See* UK Substituted Compliance Notice and Proposed Order, 86 FR at 18399, 18417. The Commission sought comment in the Reopening Release on whether this approach should be taken in the final Order. *See* Reopening Release, 86 FR at 18348.

[458] *See* Reopening Release, 86 FR at 18348 (discussing this condition). The Commission directed commenters to the UK Substituted Compliance Notice and Proposed Order to indicate how this approach would be implemented in ordering language. *See also* UK Substituted Compliance Notice and Proposed Order, 86 FR 18395, 18415–20.

[459] The Commission included the Rule 18a–1 condition in the UK Substituted Compliance Notice and Proposed Order as part of the substituted compliance determination for the daily trading records requirement of Exchange Act section 15F(g). UK Substituted Compliance Notice and Proposed Order, 86 FR at 18420. A commenter asked that the condition be modified so that it applies only if the Covered Entity is not prudentially regulated (and therefore subject to Rule 18a–1). SIFMA UK Letter at 23. Instead, the Commission has determined to delete this condition from the substituted compliance determination with respect to Exchange Act section 15F(g) generally because the requirements of Exchange Act section 15 F(g) are not important for monitoring or examining for

Fifth, the proposed Order included a condition that Covered Entities must promptly furnish to a representative of the Commission upon request an English translation of any record, report, or notification of the Covered Entity that is required to be made, preserved, filed, or subject to examination pursuant to Exchange Act section 15F of this Order.[460] In response, commenters requested that the Commission provide a time period for furnishing such translations that is commensurate with the scope of the Commission's request.[461] Records requested by the Commission staff must be provided promptly. Requests for translations of those records may require additional time. The facts and circumstances of a particular requests (*i.e.,* the volume of records requested and the extent to which they contain narrative text as opposed to figures) will implicate the timing of production. Therefore, the Commission does not believe it would be appropriate to prescribe a timeframe for production. The Commission is adopting the English translation requirement in paragraph (f)(7) of the final Order as proposed.

Sixth, the Commission conditioned substituted compliance with Exchange Act rule 18a–7 on Covered Entities filing periodic unaudited financial and operational information with the Commission or its designee in the manner and format required by Commission rule or order. Commenters made suggestions about the scope and requirements of such a Commission order or rule in addition to reiterating comments previously made in response to the same condition in the German order.[462] First, if SBS Entities are required to prepare FOCUS Report Part II, and a positive substituted compliance determination is made with respect to the Commission's capital requirements, a commenter proposed that the Commission permit an SBS Entity to submit capital computations in a manner consistent with its home country capital standards and related reporting rules.[463] Second, some commenters asked that Covered Entities be permitted to file their unaudited financial information less frequently (*e.g.,* quarterly) and provide a later submission deadline to match the frequency of reporting and reporting deadline required by the Covered Entity's home country regulator,[464] while other comment urged that Covered Entities be subject to monthly instead of quarterly reporting of their financial condition.[465] Third, commenters supported a potential approach identified by the Commission under which Covered Entities would be permitted to satisfy their Exchange Act rule 18a–7 obligations for a two-year period by filing the FOCUS Report Part IIC with only a limited number of the required line items completed.[466] Fourth, the Commission received comment recommending that the FOCUS Report be modified to omit certain line items either permanently or during a two-year transition.[467] The Commission will consider these comments as it works towards completing a Commission order or rule pursuant to the provision in this Order that substituted compliance with respect to Exchange Act rule 18a–7's FOCUS Report filing requirement is conditioned on Covered Entities filing unaudited financial and operational information in the manner and format specified by Commission order or rule. The Commission will consider these comments as it works towards completing a Commission order or rule pursuant to the provision in this Order that substituted compliance with respect to Exchange Act rule 18a–7's FOCUS Report filing requirement is conditioned on Covered Entities filing unaudited financial and operational information in the manner and format specified by Commission order or rule.

Seventh, the Commission's positive substituted compliance determination for Exchange Act rule 18a–7 identifies a number of conditions regarding the requirement to file annual audited reports pursuant to Exchange Act rule 18a–7. The third condition states SBS Entities that are not required under French or EU laws to file a report of an independent public accountant covering their financial statements must file such an accountant's report. In its proposal, the Commission requested comment on whether the independent public accountant must meet the Commission's independence standards for public accountants. The Commission did not receive comment on this point, but to ensure that the SBS Entity's accountant is subject to independence standards, the Commission is adding to the third condition the requirement that the SBS Entity's accountant complies with French independence requirements.[468]

Eighth, in its proposal, the Commission requested comment on whether there are any French SBS Entities that are not expected to be exempt from Exchange Act rule 18a–4, and therefore should be required to file certain supporting schedules under Exchange Act rule 18a–7 that relate to Exchange Act rule 18a–4. The Commission did not receive comment on this point, but in case such entities exist, paragraph (f)(3)(E) of the Order now includes a condition requiring SBS Entities to file with the Commission the supporting schedules required by Exchange Act rule 18a–7(c)(2)(ii) and (iii) that relate to Exchange Act rule 18a–4 (*i.e.,* Computation for Determination of Security-Based Swap Customer Reserve Requirements and Information Relating to the Possession or Control Requirements for Security-Based Swap Customers) if the SBS Entity is not exempt from Exchange Act rule 18a–4. Substituted compliance is not available for Exchange Act rule 18a–4 and, therefore, this condition is designed to provide the Commission with similar compliance information.

The Commission also received comment suggesting certain modifications to the ordering language. Specifically, a commenter suggested revising paragraph (f)(4) of the French Substituted Compliance Notice and Proposed Order, which requires a Covered Entity to send a copy of any notice required to be sent by EU and French laws cited in paragraph (f)(4) simultaneously to the Commission. The commenter recommended revising this provision to require the notices that a Covered Entity would be required to send to the Commission be limited to those notices required by EU and French law that are comparable to Exchange Act rule 18a–8(d) instead of the entirety of Exchange Act rule 18a–8. Furthermore, the commenter recommended conditioning the requirement to provide these notices to the Commission to be limited to those notifications that are related to (1) a breach of the EU and French laws cited in the relevant portions of paragraphs

compliance with Exchange Act rule 18a–1. Therefore, all Covered Entities—whether or not subject to Exchange Act rule 18a–1—can apply substituted compliance with respect to Exchange Act section 15F(g).

[460] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85734 (discussing this condition).

[461] *See* FBF Letter at 2; SIFMA Letter I at 14.

[462] *See* SIFMA Letter I at 15; SIFMA Letter II at Appendix B.

[463] *See* SIFMA Letter I at 15.; SIFMA Letter II at Appendix B. *See also* FBF Letter at 3 (supporting the SIFMA Letter I's observations and recommendations that would provide additional flexibility for SBS Entities with respect to their financial reporting obligations).

[464] *See* SIFMA Letter I at 15–16; SIFMA Letter II at Appendix B. *See also* FBF Letter at 3 (supporting the SIFMA Letter I's observations and recommendations that would provide additional flexibility for SBS Entities with respect to their financial reporting obligations).

[465] *See* AFR Letter at 1.

[466] *See* SIFMA Letter I at 16; SIFMA Letter II at Appendix B; FBF Letter at 3.

[467] *See* SIMA Letter II at Appendix B.

[468] *See* para. (f)(3)(iii)(C) of the Order.

(f)(1) or (2) of the Order, which, in the case of a Covered Entity that is prudentially regulated, also relates to the Covered Entity's business as a security-based swap dealer or major security-based swap participant, or (2) a deficiency relating to capital requirements.[469] The commenter reasoned that the provisions of EU and French law requiring notification contained in paragraph (f)(4) require notification of a far wider array of matters than those described in Exchange Act rule 18a–8. The Commission disagrees. Exchange Act rule 18a–8 requires security-based swap dealers and major security-based swap participants for which there is no prudential regulator to notify the Commission of a failure to meet minimum net capital. Exchange Act rule 18a–8 also specifies several events that trigger a requirements that a security-based swap dealer or major security-based swap participant for which there is no prudential regulator must sent notice within twenty-four hours to the Commission. These notices are designed to provide the Commission with ''early warning'' that the SBS entity may experience financial difficulty. Furthermore, Exchange Act rule 18a–8 requires bank security-based swap dealers to give notice to the Commission when it files an adjustment of its reported capital category with its prudential regulator. Additional notification requirements arise with respect to the failure to maintain and keep current required books and records, the discovery of material weaknesses, and failure to make a required deposit into the special reserve account for the exclusive benefit of security-bases swap customers.[470] While the specific EU and French requirements cited with respect to Exchange Act rule 18a–8 are different from the specific requirements set forth in Exchange Act rule 18a–8, the Commission believes the EU and French notice requirements cited in paragraph (f)(4) of the Order provide for comparable regulatory outcomes by requiring notification of events or conditions which may impact an SBS Entity's capital or signal the potential for financial difficulty, indicate the failure to maintain and keep current books and records, or the potential for the failure to comply with other requirements related to the protection of customer assets. The recommended revisions would reduce the scope of notifications the Commission would receive. Consequently, the Commission is not making the recommended revisions with respect to paragraph (f)(4).

The commenter also recommended revising paragraphs (f)(2)(i)(H)(*1*), (f)(3)(i)(A), and (f)(3)(ii)(A) to include the qualifier ''as applicable'' with respect to citations to CRR Reporting ITS annexes. The commenter stated that not all firms submit all of the CRR Reporting ITS annexes.[471] Accordingly, the Commission is modifying these paragraphs to include the qualifier ''as applicable.''[472]

2. Citations to EU and French Law

The Commission also received comment recommending changes to the French Substituted Compliance Notice and Proposed Order to refine the scope of French law provisions that would operate as conditions to substituted compliance.[473] The Commission reviewed each of the EU or French law citations that the commenter recommended adding or removing from the Order for relevance to the comparable Exchange Act requirement while also keeping in mind that each EU or French law citation was included in the French Authorities' Application intentionally. The Commission's conclusion and reasoning with respect to the commenter's recommendations is discussed in further detail below. In addition to refining the scope of EU and French law citations in response to comment, the Order reflects changes to the EU and French law citations after cite checking the EU and French law provisions in the French Substituted Compliance Notice and Proposed Order against the EU and French law provisions cited in the French Authorities' Application, as well as the UK implementation of the EU law provisions cited in the UK Proposed Order Granting Substituted Compliance in Connection with Certain Requirements Applicable to Non-U.S. Security-Based Swap Dealers and Major Security-Based Swap Participants Subject to Regulation in the French Republic.

a. Global

The commenter recommended deleting references to MiFID Org Reg, reasoning that these provisions could raise issues due to the discrepancy between Exchange Act requirements, which apply on an entity-level basis, and these EU requirements, which are territorially limited. As explained in part III.C. above, conducting business outside France does not preclude a firm from relying on substituted compliance for the business it conducts within France. Accordingly, unless specified otherwise below, the Commission is not removing references to these EU and French law requirements from the Order's list of EU and French law requirements comparable to the Commission's recordkeeping, reporting, notification, and securities count requirements.

The commenter recommended deleting references to MiFID article 25(2) and MLD articles 11 and 13 and their French implementing provisions, which relate to customer information and suitability requirements, reasoning that these provisions do not correspond to, and go beyond, the Commission's recordkeeping, reporting, notification, and securities count requirements. The Commission agrees with the commenter's reasoning, except with respect to Exchange Act rule 18a–5(a)(7) and (b)(7) (customer account records), Exchange Act rule 18a–5(a)(17) and (b)(13) (suitability record creation), and Exchange Act rule 18a–6 (b)(1)(xii) (suitability record preservation). Therefore, the Commission is removing references to these requirements from the Order's list of EU and French law requirements comparable to the Commission's recordkeeping, reporting, notification, and securities count requirements, except for Exchange Act rules 18a–5(a)(7), (a)(17), (b)(7), and (b)(13).[474]

The commenter recommended deleting references to MiFID Org Reg article 76, MiFID article 16(7) and its French implementing provisions, and MFC article L. 533–10 III, which relate to the recording of telephone and electronic communications, reasoning that they do not correspond to, and go beyond, the requirements of the Commission's recordkeeping, reporting, notification, and securities count rules. The Commission agrees with the commenter's reasoning, except with respect to Exchange Act rules 18a–6(b)(1)(iv) and (b)(2)(ii), which relate to communications including telephonic communications. Therefore, the Commission is removing references to these requirements from the Order's list of EU and French law requirements comparable to the Commission's recordkeeping, reporting, notification, and securities count requirements,

[469] *See* SIFMA Letter II at Appendix A.

[470] *See* Exchange Act rule 18a–8, 17 CFR 240.18a–8.

[471] *See* SIFMA Letter II at Appendix A.

[472] *See* paras. (f)(2)(i)(H)(*1*), (f)(3)(i)(A), and (f)(3)(ii)(A) of the Order.

[473] *See* SIFMA Letter II at Appendix A. *See also* SIFMA Letter I at 4–7; FBF Letter at 2–3.

[474] *See* paras. (f)(1)(i)(D)(*1*), (f)(1)(i)(G)(*1*), (f)(1)(i)(I)(*1*), (f)(2)(i)(A), (f)(2)(i)(B), and (f)(2)(i)(D) of the Order.

except for Exchange Act rules 18a–6(b)(1)(iv) and (b)(2)(ii).[475]

The commenter recommended deleting references to the EBA Guidelines on Outsourcing, reasoning that they only contain nonbinding guidance. The Commission agrees with the commenter's reasoning and is therefore removing references to this requirement from the Order's list of EU and French law requirements comparable to the Commission's recordkeeping, reporting, notification, and securities count requirements.[476]

b. Exchange Act Rules 18a–5 and 18a–6

The commenter recommended deleting references to MiFIR article 25(1), which sets a duration of five years for firms to keep relevant data relating to orders and transactions in financial instruments, reasoning that this does not correspond to, and goes beyond, the requirements of Exchange Act rules 18a–5 and 18a–6. With respect to Exchange Act rule 18a–6, the five year record retention period is directly relevant to the record preservation requirement in Exchange Act rule 18a–6. With respect to Exchange Act rule 18a–5, while this requirement contains a record retention element, it also contains a record creation requirement that is relevant to Exchange Act rule 18a–5. Accordingly, the Commission is not removing references to this requirement from the Order's list of EU and French law requirements comparable to Exchange Act rules 18a–5 and 18a–6.

The commenter recommended deleting references to CRD article 73 and its French implementing provisions, reasoning that it relates to substantive capital requirements. CRD article 73 requires firms to ''have in place sound, effective and comprehensive strategies and processes to assess and maintain . . . internal capital'' which the French Authorities' Application states in practice will require ''the maintenance of full records of the Investment Firm's assets, liabilities, income and expense and capital accounts to be maintained on an on-going basis.''[477] Accordingly, the Commission is not removing references to this requirement from the Order's list of EU and French law requirements comparable to Exchange Act rules 18a–5 and 18a–6.

The commenter recommended deleting references to MiFID Delegated Directive article 2 and its French implementing provisions, reasoning that they do not relate to recordkeeping. The Commission disagrees because MiFID Delegated Directive article 2 requires, among other things, that firms ''keep records and accounts enabling them . . . to distinguish assets held for one client from assets held for any other client and from its other own assets'' which directly implicates record creation and preservation. Accordingly, the Commission is not removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rules 18a–5 and 18a–6.

The commenter recommended deleting references to EMIR article 11, which relates to timely confirmation of transactions, and EMIR article 39, which relates to a firm's requirement to segregate the positions they clear for a client with a central counterparty from their own positions, reasoning that they do not correspond to, and go beyond, the requirements of Exchange Act rules 18a–5 and 18a–6. While these requirements contain segregation and confirmation requirements, they also contain record creation requirements that are relevant to Exchange Act rule 18a–5. Accordingly, the Commission is not removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–5, except with respect to Exchange Act rule 18a–5(a)(12) for which the Commission agrees with the commenter's reasoning.[478] However, the Commission agrees these provisions do not relate to record preservation is removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–6.[479]

The commenter recommended deleting references to MiFID articles 25(5) and 25(6) and their French implementing provisions, reasoning that they do not correspond to, and go beyond, the requirements of Exchange Act rules 18a–5 and 18a–6. Both provisions contain record creation elements, because MiFID article 25(5) requires firms to ''establish a record'' setting out the rights and obligations of the firm and the client, and MiFID article 25(6) requires firms to prepare client reports ''in a durable medium.'' Accordingly, the Commission is not removing references to these requirement from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–5. However, the Commission agrees that these provisions do not relate to record preservation and is removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–6,[480] except with respect to Exchange Act rule 18a–6(d)(4) and (d)(5) which implicates record creation in addition to record preservation.[481]

The commenter recommended deleting references to CRR articles 103, 105(3), and 105(10), which relate to the firm's management of trading book exposures, reasoning that they do not correspond to, and go beyond, the requirements of Exchange Act rules 18a–5 and 18a–6. However, the French Authorities' Application states that these requirements in practice require firms to have ''a record of their long and short positions to enable these to be monitored'' which is relevant to Exchange Act rules 18a–5 and 18a–6.[482] Accordingly, the Commission is not removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rules 18a–5 and 18a–6.

The commenter recommended deleting references to MiFID article 16(6) and its French implementing provisions, reasoning that they do not correspond to, and go beyond, the requirements of Exchange Act rules 18a–5 and 18a–6. MiFID article 16(6) requires firms to ''arrange for records to be kept of all services, activities and transactions undertaken by it'' which is relevant to record creation and preservation. Accordingly, the Commission is not removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rules 18a–5 and 18a–6.

The commenter recommended deleting references to CRR article 104(1)(j) from the Order, reasoning that the provision does not exist. The Commission confirmed with the French Authorities that references to CRR article 104(1)(j) were intended to reference CRD article 104(1)(j). However, CRD article 104(1)(j) relates to

[475] *See* paras. (f)(1)(i)(A)(*1*), (f)(1)(i)(D)(*1*), (f)(1)(i)(F)(*1*), (f)(1)(i)(G)(*1*), (f)(1)(i)(I)(*1*), (f)(1)(i)(M), (f)(2)(i)(A), (f)(2)(i)(B), and (f)(2)(i)(O)(*1*) of the Order.

[476] *See* para. (f)(2)(i)(R) of the Order.

[477] *See* French Authorities' Application Annex I category 2 at 14.

[478] *See* para. (f)(1)(i)(L)(*1*) of the Order.

[479] *See* paras. (f)(2)(i)(A), (f)(2)(i)(B), (f)(2)(i)(D), (f)(2)(i)(F)(*1*), (f)(2)(i)(G)(*1*), and (f)(2)(i)(Q) of the Order.

[480] *See* para. (f)(2)(i)(P)(*1*) of the Order.

[481] *See* paras. (f)(2)(i)(A), (f)(2)(i)(B), (f)(2)(i)(C)(*1*), (f)(2)(i)(D), (f)(2)(i)(G)(*1*), (f)(2)(i)(I)(*1*), and (f)(2)(i)(O)(*1*) of the Order.

[482] *See* French Authorities' Application Annex 1 category 2 at 16.

supervisory power of authorities to impose additional reporting requirements which the Commission believes does not correspond to, and goes beyond the requirements of Exchange Act rule 18a–6. Therefore, references in the Order to CRD article 104(1)(j) and its French implementing provisions are not included.[483]

The commenter recommended deleting references to MiFID Org Reg article 59, which sets out the requirement to confirm execution of an order to the client, reasoning that it does not correspond to, and goes beyond, the requirements of Exchange Act rules 18a–5 and 18a–6. MiFID Org Reg article 59 identifies specific data elements that are relevant to the records required to be created under Exchange Act rule 18a–5, so the Commission is not removing references to this requirement from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–5. However, the Commission believes that MiFID Org Reg article 59 relates to record creation but not record preservation and is therefore removing references to this requirement from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–6.[484]

The commenter recommended adding to paragraphs (f)(1) and (f)(2) of the Order references to Internal Control Order articles 85, 86, 92, and 93, which impose audit trail requirements. The Commission agrees these requirements are relevant because they relate to record creation and preservation, and is therefore adding them to the Order's list of EU and French requirements comparable to Exchange Act rules 18a–5 and 18a–6.[485]

The commenter recommended deleting from paragraphs (f)(2)(i)(A) and (f)(2)(i)(B) of the Order references to MiFID article 69(2) and its French implementing provisions, because these provisions relate to the powers of the competent authorities rather than the obligations of the entity. The Commission disagrees, because a regulator can only ''have access to any document or data . . . relevant for the performance of its duties'' as required by MiFID article 69(2) if firms are required to preserve these documents and data. Accordingly, the Commission is not removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–6(a)(1), (a)(2), (b)(1)(i), and (b)(2)(i).

The commenter recommended adding to paragraphs (f)(2)(I)(*1*) and (f)(2)(J)(*1*) of the Order references to Internal Control Order articles 94 through 96 and 99 through 102, which require firms to implement risk analysis, measurement and management systems. The Commission agrees these requirements are relevant because these systems in practice will require preservation of risk management and counterparty credit risk records, and is therefore adding them to the Order's list of EU and French requirements comparable to Exchange Act rules 18a–6(b)(1)(ix) and (b)(1)(x).[486]

The commenter recommended replacing in paragraph (f)(1)(i)(K) of the Order references to MiFID Org Reg article 21(1)(a) with references to MiFID Org Reg article 21(1)(d) due to an incorrect reference in the French Authorities' Application with respect to Exchange Act rule 18a–5(a)(10) and (b)(8). The Commission agrees with the commenter's reasoning and is therefore replacing references to MiFID Org Reg article 21(1)(a) with references to MiFID Org Reg article 21(1)(d) in the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–5(a)(10) and (b)(8).[487]

The commenter recommended replacing in paragraphs (f)(1)(i)(N)(*1*) and (f)(1)(i)(O)(*1*) of the Order references to EMIR RTS article 15(1) with EMIR RTS article 15(1)(a) with respect to Exchange Act rule 18a–5(a)(18) and (b)(14) because the remainder of article 15(1) does not include a record creation requirement. The Commission agrees with the commenter's reasoning and is therefore replacing references to EMIR RTS article 15(1) with EMIR RTS article 15(1)(a) in the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–5(a)(18) and (b)(14).

The commenter recommended deleting from paragraph (f)(2)(E)(*1*) of the Order references to CRR and CRR Reporting ITS, which relate to supervisory reports to be made, reasoning that they do not correspond to, and go beyond, the requirements of Exchange Act rule 18a–6(b)(1)(v). Although these laws relate to reporting requirements, the information required to be included in these reports is relevant to the records required by Exchange Act rule 18a–6(b)(1)(v). In addition, the French Authorities' Application specifically cites these requirements as comparable to Exchange Act rule 18a–6(b)(1)(v).[488] Accordingly, the Commission is not removing references to this requirement from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–6(b)(1)(v).

The commenter recommended adding to paragraphs (f)(2)(i)(F) and (f)(2)(i)(K)(*1*) of the Order a reference to MFC article L. 561–12 with respect to Exchange Act rules 18a–6(b)(1)(vi) and (b)(2)(iii) (records of discretionary authority for security-based swap accounts) and (b)(1)(xii) and (b)(2)(vii) (business conduct records). The Commission agrees this provision is relevant because it requires firms to keep documents relating to business relationships and customers for 5 years after an account is closed. Therefore, the Commission is adding MFC article L. 561–12 to the Order's list of EU and French requirements comparable to Exchange Act rules 18a–6(b)(1)(vi), (b)(1)(xii), (b)(2)(iii), and (b)(2)(vii).[489]

The commenter recommended deleting from paragraph (f)(2)(i)(I)(*1*) of the Order references to CRR articles 286 and 293(1)(d), which relate to the use of internal models for credit risk, reasoning that they do not correspond to, and go beyond, the requirements of Exchange Act rule 18a–6(b)(1)(ix). The ''policies, processes and systems'' (with respect to CRR article 286) and ''adequate resources [ ] devoted to credit and counterparty risk control'' (with respect to CRR article 293(1)(d)) in practice require firms to maintain records relevant to Exchange Act rule 18a–6(b)(1)(ix). Accordingly, the Commission is not removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–6(b)(1)(ix).

The commenter recommended deleting from paragraph (f)(2)(i)(I)(*1*) of the Order references to EMIR RTS, reasoning that referencing an entire law without referencing a specific provision does not correspond to, and goes beyond, the requirements of Exchange Act rule 18a–6(b)(1)(ix). This provision is cited by the French Authorities' Application as directly relevant because it requires firms to have ''formalised processes'' ''to measure, monitor and mitigate operational risk and

[483] *See* paras. (f)(2)(i)(E)(*1*) and (f)(2)(i)(H)(*1*) of the Order.

[484] *See* paras. (f)(2)(i)(A), (f)(2)(i)(B), (f)(2)(i)(D), and (f)(2)(i)(G)(*1*) of the Order.

[485] *See* paras. (f)(1)(i)(A)(*1*), (f)(1)(i)(B)(*1*), (f)(1)(i)(D)(*1*), (f)(1)(i)(F)(*1*), (f)(1)(i)(G)(*1*), (f)(1)(i)(H)(*1*), (f)(1)(i)(I)(*1*), (f)(1)(i)(K), (f)(1)(i)(N)(*1*), (f)(1)(i)(O)(*1*), (f)(2)(i)(C)(*1*), (f)(2)(i)(D), (f)(2)(i)(E)(*1*), and (f)(2)(i)(H)(*1*) of the Order.

[486] *See* paras. (f)(2)(i)(I)(*1*) and (f)(2)(i)(J)(*1*) of the Order.

[487] *See* para. (f)(1)(i)(K) of the Order.

[488] *See* French Authorities' Application Annex I category 2 at 51–52.

[489] *See* paras. (f)(2)(i)(F) and (f)(2)(i)(K)(*1*) of the Order.

counterparty credit risk,'' [490] which is relevant to Exchange Act rule 18a–6(b)(1)(ix). Accordingly, the Commission is not removing references to this requirement from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–6(b)(1)(ix).

The commenter recommended removing from paragraph (f)(2)(i)(I)(*1*) of the Order the reference to CRD articles 75 through 87 and their French implementing provisions, reasoning that these provisions cover various capital matters that do not correspond to, and go beyond, the requirements of Exchange Act rule 18a–6(b)(1)(ix). The Commission disagrees, because these provisions are cited in the French Authorities' Application as directly relevant due to the ''risk management arrangements, policies and procedures required to be implemented'' under these provisions.[491] Accordingly, the Commission is not removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–6(b)(1)(ix).

The commenter recommended deleting from paragraphs (f)(1)(i)(K) and (f)(2)(i)(M) of the Order (employment application record creation and preservation) references to MiFID articles 9(1) and 16(3) and their French implementing provisions, reasoning that these provisions do not relate to recordkeeping. Both provisions require recordkeeping in practice through their requirements to monitor conflicts of interest. Accordingly, the Commission is not removing references to these requirements from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–5(a)(10) and (b)(8) and Exchange Act rule 18a–6(d)(1).

The commenter recommended adding to paragraphs (f)(2)(i)(L) and (f)(2)(i)(O) of the Order the reference to MiFID Org Reg article 21(1)(f) with respect to Exchange Act rules 18a–6(c) (organizational records) and (d)(3) (compliance records). The Commission agrees this provision is relevant because it requires firms to ''maintain adequate and orderly records of their business and internal organization.'' Therefore, the Commission is adding MiFID Org Reg article 21(1)(f) of the Order's list of EU and French requirements comparable to Exchange Act rule 18a–6(c) and (d)(3).[492]

c. Exchange Act Rule 18a–7

The commenter recommended deleting from paragraphs (f)(3)(i)(A) and (f)(3)(ii)(A) references to CRD article 104(1)(j) relating to supervisory power of authorities to impose additional reporting requirements, reasoning that this provision does not correspond to, and goes beyond the requirements of Exchange Act rule 18a–7(a)(1) and (a)(2), and (a)(3). The Commission agrees. Accordingly, the Commission is removing references to these requirements and references to related implementing regulations MFC article L. 612–24 and Decree of 20 February 2007 relating to prudential requirements article 6 from the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–7(a)(1) and (a)(2).[493]

The commenter recommended deleting from paragraph (f)(3)(ii)(A) references to CRR articles 431 through 455 relating to public disclosures, reasoning that such provisions do not relate to regulatory reporting. However, the French Authorities' Application cites CRR articles 431, 433, 452, 454, and 455 as requiring, among other things, firms to make ''Pillar III' disclosures which include information on the use of capital models and matters such as credit risk, the exposure values by class of exposures subject to evaluation using models, and internal controls on the development and use of models.[494] This information is relevant to Rule 18a–7(a)(3) and 18a–7(j). Accordingly, the Commission is removing references to CRR articles 431 through 455 except for CRR articles 431, 433, 452, 454, and 455 in the Order's list of EU and French law requirements comparable to Exchange Act rule 18a–7(a)(3) and 18a–7(j).[495]

The commenter recommended deleting from paragraph (f)(3)(ii)(A) references to Accounting Directive article 34, French Commerce Code articles L. 232–1, R. 232–1 through R. 232–8, and L. 823–1 through L. 823–8–1, relating to general publication requirements for financial statements, and to the appointment of external financial auditors. The commenter reasoned that these provisions do not correspond to, and go beyond, the requirements of Exchange Act rule 18a–7(a)(3) and 18a–7(j). The Commission agrees. Accordingly, the Commission is removing references to these EU and French law requirements in the Order's list of requirements comparable to Exchange Act rule 18a–7(a)(3) and 18a–7(j).[496]

The commenter recommended deleting from paragraph (f)(3)(iii) references to CRR articles 435–436, 441, 444, and 450 (stating that these provisions are not in the UK Proposed Order), as well as Accounting Directive article 34, and French Commerce Code articles L. 232–1, R. 232–1 through R. 232–8, L. 823–1 through L. 823–8–1. The commenter reasoned that these provisions do not correspond to, and go beyond, the requirement requirements of Exchange Act rule 18a–7(b). The Commission disagrees. The French Authorities' Application states that pursuant to CRR articles 431 to 455, CRR firms are required to make ''Pillar III'' public disclosures at least annually in connection with the publication, and that such disclosures cover a variety of matters including, among other things, capital resources and capital requirements. Furthermore, in referencing CRR articles 431 to 455, the French Authorities' Application states that the requirements are comparable to analogous requirements under relevant provisions of Exchange Act rule 18a–7(b).[497] Accordingly, the references to these EU and French law requirements, and is instead including references to CRR articles 431 to 455 in the Order's list of requirements comparable to Exchange Act rule 18a–7(b).[498] With respect to Accounting Directive article 34, and French Commerce Code articles L. 232–1, R. 232–1 through R. 232–8, L. 823–1 through L .823–8–1, the Commission agrees with the commenter regarding references to Accounting Directive article 34, but disagrees with respect to the references to French Commerce Code L. 232–1, R. 232–1 through R. 232–8, L. 823–1 through L. 823–8–1. The French Authorities' Application states that credit institutions and investment firms must have their financial statements audited, and must publish their financial statements and management report annually pursuant to Accounting Directive articles 30 and 34. These requirements are relevant to Exchange Act rule 18a–7(b). Accordingly, the Commission is deleting references to Accounting Directive article 34, but is not deleting reference to French Commerce Code L. 232–1, R. 232–1 through R. 232–8, L. 823–1 through L. 823–8–1 in the Order's list of

[490] *See* French Authorities' Application Annex I category 2 at 60.

[491] *See* French Authorities' Application Annex I category 2 at 58–59.

[492] *See* paras. (f)(2)(i)(L) and (f)(2)(i)(O)(*1*) of the Order.

[493] *See* paras. (f)(3)(i)(A) and (f)(3)(ii)(A) of the Order.

[494] *See* French Authorities' Application Annex I Category 2 at 91–93.

[495] *See* para. (f)(3)(ii)(A) of the Order.

[496] *See* para. (f)(3)(ii)(A) of the Order.

[497] *See* French Authorities' Application Annex I at 93–94.

[498] *See* para. (f)(3)(iii) of the Order.

requirements comparable to Exchange Act rule 18a–7(b).[499]

The commenter recommended deleting references in paragraph (f)(3)(iv)(A) references to MiFID Org Reg article 72(2) and Annex I, which relate to recordkeeping requirements. The Commission notes that MiFID Org Reg article 72(2) and Annex I are not cited in connection with the EU and French law requirements in the Order's list of requirements comparable to Exchange Act rule 18a–7(b). The commenter also recommended deleting reference to CRR and CRD articles which set out specific capital requirements. With respect to CRD article 89, the Commission agrees as this provision requires member states to impose specified disclosure requirements on institutions. Accordingly, the Commission is deleting reference to this requirement in the Order's list of requirements comparable to Exchange Act rule 18a–7(c) through (h).[500] With respect to the cited CRR provisions, the Commission disagrees. The French Authorities' Application states that CRR article 26(2) relates to the inclusion of a firm's interim or year-end profits in Common Equity Tier 1 capital and the associated requirement that such profits be verified by persons independent of the firm, and that CRR articles 132(5) and 154 set forth requirements for a firm to engage an external auditor to confirm the accuracy of information regarding the firm's calculations with respect to average risk weights for certain exposures which is comparable to the requirements under Exchange Act rules 18a–7(c)(1)(i)(C) and 18a–7(d) through (g). Furthermore the French Authorities' Application states that, for firms using internal models to calculate credit risk, operational risk, market risk exposures, or market risk capital requirement, CRR articles 191, 321, 325bi, and 368 require various levels of internal or external audit and/or review of the models, systems, and/or operations. The French Authorities' application notes where investment firm's rely on a depository or management company of a collective investment undertaking, CRR articles 418, 350 and 353 require the investment firm to calculate and report own funds requirements for the market value of haircuts, and position risk with respect to positions in specified instruments.[501] As a result, the French Authorities' Application states that the EU report review requirements provide for comparable regulatory outcomes to the SEC report review requirements, as both regulatory regimes require firms to submit reports by independent auditors on the firm's financial and operational information in order to ensure the accuracy of information and protect market participants. The Commission believes these provisions are relevant to Rule 18a–7(c), (d), (e), (f), (g), and (h). Accordingly, the Commission is not deleting references to these EU and French law in the Order's list of requirements comparable to Exchange Act rule 18a–7(c) through (h).[502]

The commenter recommended deleting references to Accounting Directive article 34 from paragraph (f)(3)(iv)(A), stating that this provision sets out accounting and publication requirements applicable to corporations generally, and is not enforced by the ACPR or the AMF, and reasons that the provision does not correspond to, and goes beyond, the requirements of Exchange Act rule 18a–7 (c) through (h). The commenter suggests replacing this provision instead with MFC articles L. 511–35 to L. 511–38, setting forth accounting and publication obligations for credit institutions, and article L. 533–5 which sets forth accounting and publication obligations for investment firms. With respect to Accounting Directive article 34, the Commission agrees. As a result, the Commission is deleting reference to Accounting Directive article 34 from the Order's list of requirements comparable to Exchange Act rule 18a–7(c) through (h).[503] With respect to the commenter's recommendation regarding MFC articles L. 511–35 to L. 511–38, and article L. 533–5, the Commission agrees and, accordingly, is including references to these provisions in the Order's list of requirements comparable to Exchange Act rule 18a–7(c) through (h).[504]

The commenter recommended deleting references in paragraph (f)(3)(iv)(A) to MiFID articles 16(8) through (10). The commenter reasoned that these provisions contain substantive, not reporting requirements, and do not correspond to, and go beyond, the requirements of Exchange Act rules 18a–7(c) through (h). The Commission agrees and is not including references to these provisions in the Order's list of requirements comparable to Exchange Act rules 18a–7(c) through (h).[505]

d. Exchange Act Rule 18a–8

The commenter recommended deleting references MiFID article 73, and CRD article 71 (as well as the implementing provisions) from paragraphs (f)(4)(i)(A)(*1*), (f)(4)(i)(B), (f)(4)(i)(C)(*1*), and (f)(4)(i)(D)(*1*), reasoning that these provisions do not correspond to, and go beyond, the requirements of Exchange Act Rule 18a–8(a)(1)(i), (a)(1)(ii), (b)(1), (b)(2), (b)(4), (c), (d), (e), and (h). The Commission agrees with respect to references to MiFID article 73 and CRD article 71, but disagrees with respect to the implementing provisions. The French Authorities' Application cite the implementing provisions as providing for comparable regulation outcomes to the Commission's notice requirements as both regimes aim to establish reporting mechanisms so that regulators will be promptly notified of relevant events. The Commission believes the implementing provisions, MFC articles L. 511–33II, L. 634–1, and L. 634–2, are relevant to the requirements of Exchange Act Rule 18a–8(a)(1)(i), (a)(1)(ii), (b)(1), (b)(2), (b)(4), (c), (d), (e), and (h). Accordingly, the Commission is deleting references to MiFID article 73 and CRD article 71, but is not deleting references to the implementing regulations MFC articles L. 511–33II, L. 634–1, and L. 634–2, from the Order's list of requirements comparable to Exchange Act rule 18a–8(a)(1)(i), (a)(1)(ii), (b)(1), (b)(2), (b)(4), (c), (d), (e), and (h).[506]

The commenter recommended including references to Internal Control Order 249 and 249–1 in paragraphs (f)(4)(i)(A)(*1*), (f)(4)(i)(B), (f)(4)(i)(C)(*1*), and (f)(4)(i)(D)(*1*). The Commission agrees. Accordingly, the Commission is adding references to Internal Control Order 249 and 249–1 to the Order's list of requirements comparable to Exchange Act rule 18a–8(a)(1)(i), (a)(1)(ii), (b)(1), (b)(2), (b)(4), (c), (d), (e), and (h).[507]

e. Exchange Act Rule 18a–9

The commenter recommended deleting references to MiFID Org Reg articles 74 and 75, from paragraph (f)(5)(*1*), reasoning that these provisions relate to recordkeeping requirements and therefore go beyond the requirements of Exchange Act rule 18a–9. The Commission agrees. Accordingly, the Commission is removing references to these requirements from the Order's list of EU and French law requirements

[499] *See* para. (f)(3)(iii) of the Order.

[500] *See* para. (f)(3)(iv)(A) of the Order.

[501] *See* French Authorities' Application Annex I categories 2 and 4 at 99–102.

[502] *See* para. (f)(3)(iv)(A).

[503] *See* para. (f)(3)(iv)(A) of the Order.

[504] *See* para. (f)(3)(iv)(A) of the Order.

[505] *See* para. (f)(3)(iv)(A) of the Order.

[506] *See* paras. (f)(4)(i)(A)(*1*), (f)(4)(i)(B), (f)(4)(i)(C)(*1*), and (f)(4)(i)(D)(*1*) of the Order.

[507] *See* paras. (f)(4)(i)(A)(*1*), (f)(4)(i)(B), (f)(4)(i)(C)(*1*), and (f)(4)(i)(D)(*1*) of the Order.

comparable to Exchange Act rule 18a–9.[508]

f. Exchange Act Section 15F(g)

The commenter recommended including references to MiFID Org Reg articles 21(1)(f), 21(4), and 72(1) in paragraph (f)(6). The Commission agrees. These provisions require investment firms to maintain adequate and orderly business and internal organization records, have policies and procedures in place enabling them to deliver to a competent authority in a timely manner financial reports reflecting a true and fair view of the investment firm's financial position, and retain specified records. The Commission believes that these provisions are relevant to the requirements of Exchange Act section 15F(g). Accordingly, the Commission is adding citations to these provisions in the Order's list of requirements comparable to Exchange Act section 15F(g).

IX. Supervisory and Enforcement Considerations

A. Proposed Approach

Exchange Act rule 3a71–6(a)(2)(i) provides that the Commission's assessments regarding the comparability of foreign requirements in part should take into account ''the effectiveness of the supervisory program administered, and the enforcement authority exercised'' by the foreign financial regulatory authority. This provision is intended to help ensure that substituted compliance is not predicated on rules that appear high-quality on paper if market participants in practice are allowed to fall short of their obligations, while also recognizing that differences among supervisory and enforcement regimes should not be assumed to reflect flaws in one regime or another.[509] The French Authorities' Application accordingly included information regarding the supervisory and enforcement framework applicable to derivatives markets and market participants in France.

In proposing to grant substituted compliance in connection with the French Authorities' Application, the Commission preliminarily concluded that the relevant supervisory and enforcement considerations were consistent with substituted compliance. That preliminary conclusion took into account information regarding the French Authorities' and the ECB's roles and practices in supervising investment firms and credit institutions located in France, as well as their enforcement-related authority and practices.[510]

B. Commenter Views and Final Provisions

Commenters did not address the Commission's preliminary conclusions regarding supervisory and enforcement considerations, and the Commission continues to conclude that the relevant supervisory and enforcement considerations in France are consistent with substituted compliance. In particular, based on the available information regarding the French Authorities' and the ECB's authority and practices to oversee market participants' compliance with applicable requirements and to take action in the event of violations, the Commission remains of the view that, consistent with rule 3a71–6, comparability determinations reflect French and EU requirements as they apply in practice.

To be clear, the supervisory and enforcement considerations addressed by rule 3a71–6 do not mandate that the Commission make judgments regarding the comparative merits of U.S. and foreign supervisory and enforcement frameworks, or to require specific findings regarding the supervisory and enforcement effectiveness of a foreign regime. The rule 3a71–6 considerations regarding supervisory and enforcement effectiveness instead address whether comparability analyses related to substituted compliance reflect requirements that market participants must follow, and for which market participants are subject to enforcement consequences in the event of violations. Those considerations are satisfied here.

X. Conclusion

It is hereby determined and ordered, pursuant to rule 3a71–6 under the Exchange Act, that a Covered Entity (as defined in paragraph (g)(1) of this Order) may satisfy the requirements under the Exchange Act that are addressed in paragraphs (b) through (f) of this Order so long as the Covered Entity is subject to and complies with relevant requirements of the French Republic and the European Union and with the conditions of this Order, as amended or superseded from time to time.

(a) General Conditions

This Order is subject to the following general conditions, in addition to the conditions specified in paragraphs (b) through (f):

(1) *Activities as MiFID ''investment services or activities.''* For each condition in paragraphs (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, provisions of MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions, the Covered Entity's relevant security-based swap activities constitute ''investment services'' or ''investment activities,'' as defined in MiFID article 4(1)(2) and in MFC L. 321–1, and fall within the scope of the Covered Entity's authorization from the AMF or from the ACPR after approval by the AMF of the Covered Firm's program of operations to provide investment services and/or perform investment activities in the French Republic.

(2) *Counterparties as MiFID ''clients.''* For each condition in paragraphs (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, provisions of MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions, the relevant counterparty (or potential counterparty) to the Covered Entity is a ''client'' (or potential ''client''), as defined in MiFID article 4(1)(9) and as used in the relevant provision of MFC.

(3) *Security-based swaps as MiFID ''financial instruments.''* For each condition in paragraphs (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of MiFID, provisions of MFC that implement MiFID and/or other EU and French requirements adopted pursuant to those provisions, the relevant security-based swap is a ''financial instrument,'' as defined in MiFID article 4(1)(15) and in MFC L. 211–1 and D. 211–1A.

(4) *Covered Entity as CRD/CRR ''institution.''* For each condition in paragraph (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, the provisions of CRD, provisions of MFC that implement CRD, CRR and/or other EU and French requirements adopted pursuant to those provisions, the Covered Entity is an ''institution,'' as defined in CRD article 3(1)(3) and CRR article 4(1)(3), and is either a credit institution or finance company, each as defined in MFC L. 511–1.

(5) Counterparties as EMIR ''counterparties.'' For each condition in paragraphs (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of EMIR, EMIR RTS, EMIR Margin RTS, and/or other EU

[508] *See* para. (f)(5)(*1*) of the Order.

[509] *See* French Substituted Compliance Notice and Proposed Order, 85 FR at 85734.

[510] *Id.* at 85734–36.

requirements adopted pursuant to those provisions, if the relevant provision applies only to the Covered Entity's activities with specified types of counterparties, and if the counterparty to the Covered Entity is not any of the specified types of counterparty, the Covered Entity complies with the applicable condition of this Order:

(i) As if the counterparty were the specified type of counterparty; in this regard, if the Covered Entity reasonably determines that the counterparty would be a financial counterparty if it were established in the EU and authorized by an appropriate EU authority, it must treat the counterparty as if the counterparty were a financial counterparty; and

(ii) Without regard to the application of EMIR article 13.

(6) Security-based swap status under EMIR. For each condition in paragraphs (b) through (f) of this Order that requires the application of, and the Covered Entity's compliance with, provisions of EMIR and/or other EU requirements adopted pursuant to those provisions, either:

(i) The relevant security-based swap is an ''OTC derivative'' or ''OTC derivative contract,'' as defined in EMIR article 2(7), that has not been cleared by a central counterparty and otherwise is subject to the provisions of EMIR article 11, EMIR RTS articles 11 through 15, and EMIR Margin RTS article 2; or

(ii) The relevant security-based swap has been cleared by a central counterparty that is authorized or recognized to clear derivatives contracts by a relevant authority in the EU.

(7) *Memorandum of Understanding with the French Authorities.* The Commission and the AMF and the ACPR have a supervisory and enforcement memorandum of understanding and/or other arrangement addressing cooperation with respect to this Order at the time the Covered Entity complies with the relevant requirements under the Exchange Act via compliance with one or more provisions of this Order.

(8) *Memorandum of Understanding Regarding ECB-Owned Information.* The Commission and the ECB have a supervisory and enforcement memorandum of understanding and/or other arrangement addressing cooperation with respect to this Order as it pertains to information owned by the ECB at the time the Covered Entity complies with the relevant requirements under the Exchange Act via compliance with one or more provisions of this Order.

(9) *Notice to Commission.* A Covered Entity relying on this Order must provide notice of its intent to rely on this Order by notifying the Commission in writing. Such notice must be sent to the Commission in the manner specified on the Commission's website. The notice must include the contact information of an individual who can provide further information about the matter that is the subject of the notice. The notice must also identify each specific substituted compliance determination within paragraphs (b) through (f) of the Order for which the Covered Entity intends to apply substituted compliance. A Covered Entity must promptly provide an amended notice if it modifies its reliance on the substituted compliance determinations in this Order.

(10) *European Union Cross-Border Matters.*

(i) If, in relation to a particular service provided by a Covered Entity, responsibility for ensuring compliance with any provision of MiFID or MiFIR or any other EU or French requirement adopted pursuant to MiFID or MiFIR listed in paragraphs (b) through (f) of this Order is allocated to an authority of the Member State of the European Union in whose territory a Covered Entity provides the service, the AMF or the ACPR must be the authority responsible for supervision and enforcement of that provision or requirement in relation to the particular service.

(ii) If responsibility for ensuring compliance with any provision of MAR or any other EU requirement adopted pursuant to MAR listed in paragraphs (b) through (f) of this Order is allocated to one or more authorities of a Member State of the European Union, one of such authorities must be the AMF or the ACPR.

(11) *Notification Requirements Related to Changes in Capital.* A Covered Entity that is prudentially regulated relying on this Order must apply substituted compliance with respect to the requirements of Exchange Act rule 18a–8(c) and the requirements of Exchange Act rule 18a–8(h) as applied to Exchange Act rule 18a–8(c).

(b) Substituted Compliance in Connection With Risk Control Requirements

This Order extends to the following provisions related to risk control:

(1) *Internal risk management.* The requirements of Exchange Act section 15F(j)(2) and related aspects of Exchange Act rule 15Fh–3(h)(2)(iii)(I), provided that the Covered Entity is subject to and complies with the requirements of: MiFID articles 16 and 23; MFC L. 533–2, L. 533–10.II and III, L. 533–24 and L. 533–24–1; MiFID Org Reg articles 21 through 37, 72 through 76 and Annex IV; CRD articles 74, 76, 79 through 87, 88(1), 91(1) and (2), 91(7) through (9), 92, 94 and 95; MFC L. 511–41–1–B and L. 511–41–1–C, L. 511–51, L. 511–52.I, L. 511–53, L. 511–55 through L. 511–69, L. 511–71 through 85, L. 511–89 through L. 511–97, L. 511–102, R. 511–18–2 and R. 511–16–3; Internal Control Order articles 106, 111, 114–15, 121–22, 130 through 134, 146 through 186, 211–12, 214–15; CRR articles 286 through 288 and 293; and EMIR Margin RTS article 2.

(2) *Trade acknowledgement and verification.* The requirements of Exchange Act rule 15Fi–2, provided that the Covered Entity is subject to and complies with the requirements of EMIR article 11(1)(a) and EMIR RTS article 12.

(3) *Portfolio reconciliation and dispute reporting.* The requirements of Exchange Act rule 15Fi–3, provided that:

(i) The Covered Entity is subject to and complies with the requirements of EMIR article 11(1)(b) and EMIR RTS articles 13 and 15; and

(ii) The Covered Entity provides the Commission with reports regarding disputes between counterparties on the same basis as it provides those reports to competent authorities pursuant to EMIR RTS article 15(2).

(4) *Portfolio compression.* The requirements of Exchange Act rule 15Fi–4, provided that the Covered Entity is subject to and complies with the requirements of EMIR RTS article 14.

(5) *Trading relationship documentation.* The requirements of Exchange Act rule 15Fi–5, other than paragraph (b)(5) to that rule when the counterparty is a U.S. person, provided that the Covered Entity is subject to and complies with the requirements of EMIR article 11(1)(a), EMIR RTS article 12, and EMIR Margin RTS article 2.

(c) Substituted Compliance in Connection With Capital and Margin

(1) *Capital.* The requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1, and 18a–1a through d, provided that:

(i) The Covered Entity is subject to and complies with: CRR, Part One (General Provisions) Article 6(1), Part Two (Own Funds), Part Three (Capital Requirements), Part Four (Large Exposures), Part Five (Exposures to Transferred Credit Risk), Part Six (Liquidity), and Part Seven (Leverage); MiFID Org Reg, article 23(1); BRRD, articles 45(6) and 81(1); CRD, articles 73, 79, 86, 129, 129(1), 130, 130(1), 130(5), 131, 133, 133(1), 133(4), 141,

142(1) and (2); MFC articles, 511–41–1 A, L. 511–41–1 B, L. 533–2–1, L. 533–2–2, L. 613–44, L. 613–49.I; Decree of 3 November 2014 on internal control, articles 10, 94–197, and 211–230; Decree of 3 November 2014 relating to capital buffers, articles 2, 16, 23, 56 through 62; and EMIR Margin RTS, articles 2, 3(b), 7, and 19(1)(d) and (e), (3), and (8);

(ii) The Covered Entity applies substituted compliance for the requirements of Exchange Act rules 18a–5(a)(9), 18a–6(b)(1)(x), and 18a–8(a)(1)(i), (a)(1)(ii), (b)(1), (b)(2), and (b)(4) pursuant to this Order; and

(iii)(A) The Covered Entity:

(*1*) Maintains liquid assets as defined in paragraph (c)(1)(iii)(B) that have an aggregate market value that exceeds the amount of the Covered Entity's total liabilities by at least $100 million before applying the deduction specified in paragraph (c)(1)(iii)(C) and by at least $20 million after applying the deduction specified in paragraph (c)(1)(iii)(C);

(*2*) Makes and preserves for three years a quarterly record that:

(*a*) Identifies and values the liquid assets maintained pursuant to paragraph (c)(1)(iii)(A)(*1*);

(*b*) Compares the amount of the aggregate value the liquid assets maintained pursuant to paragraph (c)(1)(iii)(A)(*1*) to the amount of the Covered Entity's total liabilities and shows the amount of the difference between the two amounts (''the excess liquid assets amount''); and

(*c*) Shows the amount of the deduction specified in paragraph (c)(1)(iii)(C) and the amount that deduction reduces the excess liquid assets amount;

(*3*) The Covered Entity notifies the Commission in writing within 24 hours in the manner specified on the Commission's website if the Covered Entity fails to meet the requirements of paragraph (c)(iii)(A)(*1*) and includes in the notice the contact information of an individual who can provide further information about the failure to meet the requirements; and

(*4*) Includes its most recent statement of financial condition filed with its local supervisor (whether audited or unaudited) with its initial written notice to the Commission of its intent to rely on substituted compliance under condition (a)(9) above.

(B) For the purposes of paragraph (c)(1)(iii)(A)(*1*), liquid assets are:

(*1*) Cash and cash equivalents;

(*2*) Collateralized agreements;

(*3*) Customer and other trading related receivables;

(*4*) Trading and financial assets; and

(*5*) Initial margin posted by the Covered Entity to a counterparty or a third-party custodian, provided:

(*a*) The initial margin requirement is funded by a fully executed written loan agreement with an affiliate of the Covered Entity;

(*b*) The loan agreement provides that the lender waives re-payment of the loan until the initial margin is returned to the Covered Entity; and

(*c*) The liability of the Covered Entity to the lender can be fully satisfied by delivering the collateral serving as initial margin to the lender.

(C) The deduction required by paragraph (c)(1)(iii)(A) is the amount of the Covered Entity's risk-weighted assets calculated for the purposes of the capital requirements identified in paragraph (c)(1)(i) divided by 12.5.

(2) *Margin.* The requirements of Exchange Act section 15F(e) and Exchange Act rule 18a–3, provided that:

(i) The Covered Entity is subject to and complies with the requirements of EMIR article 11; EMIR Margin RTS; CRR articles 103, 105(3); 105(10); 111(2), 224, 285, 286, 286(7), 290, 295, 296(2)(b), 297(1), 297(3), and 298(1); MiFID Org Reg. article 23(1); CRD articles 74 and 79(b); MFC articles L. 511–41–1–B, L. 533–2–2, L. 533–29, I al. 1, and L. 511–55 al. 1; and Decree of 3 November 2014 on internal control, article 114;

(ii) The Covered Entity collects variation margin, as defined in the EMIR Margin RTS, from a counterparty with respect to transactions in non-cleared security-based swaps, unless the counterparty would qualify for an exception from the collateral collection requirements under paragraph (c)(1)(iii) or (c)(2)(iii) of Exchange Act 18a–3;

(iii) The Covered Entity collects initial margin, as defined in the EMIR Margin RTS, from a counterparty with respect to transactions in non-cleared security-based swaps, unless the counterparty would qualify for an exception from the collateral collection requirements under paragraph (c)(1)(iii) of Exchange Act rule 18a–3; and

(iv) The Covered Entity applies substituted compliance for the requirements of Exchange Act rule 18a–5(a)(12) pursuant to this Order.

(d) Substituted Compliance in Connection With Internal Supervision and Compliance Requirements and Certain Exchange Act Section 15F(j) Requirements

This Order extends to the following provisions related to internal supervision and compliance and Exchange Act section 15F(j) requirements:

(1) *Internal supervision.* The requirements of Exchange Act rule 15Fh–3(h) and Exchange Act sections 15F(j)(4)(A) and (j)(5), provided that:

(i) The Covered Entity is subject to and complies with the requirements identified in paragraph (d)(3) of this Order;

(ii) The Covered Entity complies with paragraph (d)(4) of this Order; and

(iii) This paragraph (d) does not extend to the requirements of paragraph (h)(2)(iii)(I) to rule 15Fh–3 to the extent those requirements pertain to compliance with Exchange Act sections 15F(j)(2), (j)(3), (j)(4)(B) and (j)(6), or to the general and supporting provisions of paragraph (h) to rule 15Fh–3 in connection with those Exchange Act sections.

(2) *Chief compliance officers.* The requirements of Exchange Act section 15F(k) and Exchange Act rule 15Fk–1, provided that:

(i) The Covered Entity is subject to and complies with the requirements identified in paragraph (d)(3) of this Order;

(ii) All reports required pursuant to MiFID Org Reg article 22(2)(c) must also:

(A) Be provided to the Commission at least annually, and in the English language;

(B) Include a certification signed by the chief compliance officer or senior officer (as defined in Exchange Act rule 15Fk–1(e)(2)) of the Covered Entity that, to the best of the certifier's knowledge and reasonable belief and under penalty of law, the report is accurate and complete in all material respects;

(C) Address the Covered Entity's compliance with:

(i) Applicable requirements under the Exchange Act; and

(ii) The other applicable conditions of this Order in connection with requirements for which the Covered Entity is relying on this Order;

(D) Be provided to the Commission no later than 15 days following the earlier of:

(i) The submission of the report to the Covered Entity's management body; or

(ii) The time the report is required to be submitted to the management body; and

(E) Together cover the entire period that the Covered Entity's annual compliance report referenced in Exchange Act section 15F(k)(3) and Exchange Act rule 15Fk–1(c) would be required to cover.

(3) *Applicable supervisory and compliance requirements.* Paragraphs (d)(1) and (d)(2) are conditioned on the Covered Entity being subject to and complying with the following

requirements: MiFID articles 16 and 23; MFC articles L. 533–2, L. 533–10.II and III, L. 533–24 and L. 533–24–1; MiFID Org Reg articles 21 through 37, 72 through 76 and Annex IV; CRD articles 74, 76, 79 through 87, 88(1), 91(1) and (2), 91(7) through (9), 92, 94 and 95; and MFC L. 511–41–1–B and L. 511–41–1–C, L. 511–51, L. 511–52.I, L. 511.53, L. 511–55 through L. 511–69, L. 511–71 through 85, L. 511–89 through L. 511–97, L. 511–102, R. 511–16–2 and R. 511–16–3; Internal Control Order articles 106, 111, 114, 115, 121–22, 130–34, 146–86, 211–12, 214–15; and CRR articles 286–88 and 293; and EMIR Margin RTS article 2.

(4) *Additional condition to paragraph (d)(1).* Paragraph (d)(1) further is conditioned on the requirement that the Covered Entity complies with the provisions specified in paragraph (d)(3) as if those provisions also require compliance with:

(i) Applicable requirements under the Exchange Act; and

(ii) The other applicable conditions of this Order in connection with requirements for which the Covered Entity is relying on this Order.

(e) Substituted Compliance in Connection With Counterparty Protection Requirements

This Order extends to the following provisions related to counterparty protection:

(1) *Disclosure of information regarding material risks and characteristics.* The requirements of Exchange Act rule 15Fh–3(b) relating to disclosure of material risks and characteristics of one or more security-based swaps subject thereto, provided that the Covered Entity, in relation to that security-based swap, is subject to and complies with the requirements of MiFID article 24(4); MFC L. 533–12.II and D. 533–15; and MiFID Org Reg articles 48–50.

(2) *Disclosure of information regarding material incentives or conflicts of interest.* The requirements of Exchange Act rule 15Fh–3(b) relating to disclosure of material incentives or conflicts of interest that a Covered Entity may have in connection with one or more security-based swaps subject thereto, provided that the Covered Entity, in relation to that security-based swap, is subject to and complies with the requirements of either:

(i) MiFID articles 23(2) and (3); MFC L. 533–10.II(3); and MiFID Org Reg articles 33 through 35;

(ii) MiFID article 24(9); MFC L. 533–12–4; MiFID Delegated Directive article 11(5); and AMF General Regulation article 314–17; or

(iii) MAR article 20(1) and MAR Investment Recommendations Regulation articles 5 and 6.

(3) ''*Know your counterparty.*'' The requirements of Exchange Act rule 15Fh–3(e), as applied to one or more security-based swap counterparties subject thereto, provided that the Covered Entity, in relation to the relevant security-based swap counterparty, is subject to and complies with the requirements of MiFID article 16(2); MFC L 533–10.II(2); MiFID Org Reg articles 21 and 22, 25 and 26 and applicable parts of Annex I; CRD articles 74(1) and 85(1); MFC L. 511–55 and L. 511–41–1–B; MLD articles 11 and 13; MFC L. 561–5, L. 561–5–1, L. 561–6, L. 561–10, L. 561–4–1, R. 561–5, R. 561–5–1, R. 561–5–2, R. 561–5–4, R. 561–7, R. 561–10–3, R. 561–11–1, and R. 561–12; MLD articles 8(3) and 8(4)(a) as applied to internal policies, controls and procedures regarding recordkeeping of customer due diligence activities; and MFC L. 561–4–1 as applied to vigilance measures regarding recordkeeping of customer due diligence activities.

(4) *Suitability.* The requirements of Exchange Act rule 15Fh–3(f), as applied to one or more recommendations of a security-based swap or trading strategy involving a security-based swap subject thereto, provided that:

(i) The Covered Entity, in relation to the relevant recommendation, is subject to and complies with the requirements of MiFID articles 24(2) and (3), and 25(1) and (2); MFC L. 533–24, L. 533–24–1, L. 533–12(I), L. 533–12–6, and L. 533–13(I); and MiFID Org Reg articles 21(1)(b) and (d), 54 and 55; and

(ii) The counterparty to which the Covered Entity makes the recommendation is a ''professional client'' mentioned in MiFID Annex II section I and MFC D. 533–11 and is not a ''special entity'' as defined in Exchange Act section 15F(h)(2)(C) and Exchange Act rule 15Fh–2(d).

(5) *Fair and balanced communications.* The requirements of Exchange Act rule 15Fh–3(g), as applied to one or more communications subject thereto, provided that the Covered Entity, in relation to the relevant communication, is subject to and complies with the requirements of:

(i) Either MiFID articles 24(1) and (3) and MFC L. 533–11 and L. 533–12.I or MiFID article 30(1) and MFC L. 533–20; and

(ii) MiFID articles 24(4) and (5); MFC L. 533–12(II) and (III) and D. 533–15; MiFID Org Reg articles 46 through 48; MAR articles 12(1)(c), 15 and 20(1); and MAR Investment Recommendations Regulation articles 3 and 4.

(6) *Daily mark disclosure.* The requirements of Exchange Act rule 15Fh–3(c), as applied to one or more security-based swaps subject thereto, provided that the Covered Entity is required to reconcile, and does reconcile, the portfolio containing the relevant security-based swap on each business day pursuant to EMIR articles 11(1)(b) and 11(2) and EMIR RTS article 13.

(f) Substituted Compliance in Connection With Recordkeeping, Reporting, Notification, and Securities Count Requirements

This Order extends to the following provisions that apply to a Covered Entity related to recordkeeping, reporting, notification and securities counts:

(1)(i) *Make and keep current certain records.* The requirements of the following provisions of Exchange Act rule 18a–5, provided that the Covered Entity complies with the relevant conditions in this paragraph (f)(1)(i) and with the applicable conditions in paragraph (f)(1)(ii):

(A) The requirements of Exchange Act rule 18a–5(a)(1) or (b)(1), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 74, 75, and Annex IV; MiFIR article 25(1); and Internal Control Order articles 85, 87, 92, and 93; and

(*2*) With respect to the requirements of Exchange Act rule 18a–5(a)(1), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order.

(B) The requirements of Exchange Act rule 18a–5(a)(2), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of CRD article 73; MiFID Delegated Directive article 2; MiFID Org Reg articles 72, 74 and 75; EMIR article 39(4); MFC article L. 511–41–1B; Decree of 6 September 2017 article 3; AMF General Regulation article 312–6; and Internal Control Order articles 85, 87, 92, and 93; and

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(C) The requirements of Exchange Act rule 18a–5(a)(3) or (b)(2), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Delegated Directive article 2; MiFID Org Reg articles 72, 74 and 75;

EMIR article 39(4); Decree of 6 September 2017 article 3; and AMF General Regulation article 312–6; and

(*2*) With respect to the requirements of Exchange Act rule 18a–5(a)(3), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(D) The requirements of Exchange Act rule 18a–5(a)(4) or (b)(3), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of CRR article 103; MiFID articles 16(6), 25(5), and 25(6); MiFID Org Reg articles 59, 74, 75 and Annex IV; MiFIR article 25(1); EMIR articles 9(2) and 11(1)(a); MFC article L. 533–10 II, L. 533–14, L. 533–15; and Internal Control Order articles 85, 86, 92, and 93; and

(*2*) With respect to the requirements of Exchange Act rule 18a–5(a)(4), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(E) The requirements of Exchange Act rule 18a–5(b)(4) provided that the Covered Entity is subject to and complies with the requirements of MiFID Org Reg article 59; EMIR articles 9(2) and 11(1)(a); MiFID articles 16(6), 25(5), and 25(6); and MFC articles L. 533–10 I and II, L. 533–14, and L. 533–15;

(F) The requirements of Exchange Act rule 18a–5(a)(5) or (b)(5), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 74, 75, and Annex IV; MiFIR article 25(1); and Internal Control Order articles 85, 86, 92, and 93; and

(*2*) With respect to the requirements of Exchange Act rule 18a–5(a)(5), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(G) The requirements of Exchange Act rules 18a–5(a)(6) and (a)(15) or (b)(6) and (b)(11), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of CRR articles 103, 105(3), and 105(10); CRD article 73; MiFID articles 16(6), 25(5), 25(6); MiFID Delegated Directive article 2; MiFID Org Reg articles 59, 74, 75, and Annex IV; MiFIR article 25(1); EMIR articles 9(2), 11(1)(a), and 39(4); MFC articles L. 511–41–1–B, L. 511–51 to L. 511–88, L. 533–2–2, L. 533–10 II, L. 533–13, L. 533–14, L. 533–15; Internal Control Order articles 85, 86, 92, and 93; Ministerial Order on the Supervisory Review and Evaluation Process; Decree of 6 September 2017 article 3; and AMF General Regulation article 312–6; and

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act rule 15Fi–2 pursuant to this Order;

(H) The requirements of Exchange Act rule 18a–5(a)(7) or (b)(7), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFIR article 25(1); MLD4 articles 11 and 13; MiFID article 25(2); Internal Control Order articles 85, 86, 92, and 93; and MFC articles L. 533–13, L. 561–4–1, L. 561–5, L. 561–5–1, L. 561–6, R. 561–5, R. 561–5–1, R. 561–5–2, R. 561–5–3, R. 561–7, R. 561–10 II, R. 561–10–3, R. 561–11–1, R. 561–12, R. 561–15, R. 561–16, R. 561–18, R. 561–19; and

(*2*) With respect to the requirements of Exchange Act rule 18a–5(a)(7), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(I) The requirements of Exchange Act rule 18a–5(a)(8), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of CRR articles 103, 105(3), and 105(10); MiFID Org Reg articles 59, 74, 75 and Annex IV; MiFIR article 25(1); EMIR articles 9(2), 11(1)(a), and 39(4); MiFID articles 16(6), 25(5), and 25(6); CRD article 73; MiFID Delegated Directive article 2; MFC articles L. 511–41–1–B, L. 511–51 through L. 511–88, L. 533–2–2, L. 533–10 II, L. 533–13, L .533–14, L. 533–15; Internal Control Order articles 85, 86, 92, and 93; Ministerial Order on the Supervisory Review and Evaluation Process; Decree of 6 September 2017 article 3; and AMF General Regulation article 312–6; and

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order.;

(J) The requirements of Exchange Act rule 18a–5(a)(9), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of CRD article 73; MiFID Delegated Directive article 2; EMIR article 39(4); MiFID Org Reg articles 72, 74, and 75; MFC article L. 511–41–1B; Decree of 6 September 2017 article 3; and AMF General Regulation article 312–6;

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order; and

(*3*) This Order does not extend to the requirements of Exchange Act rule 18a–5(a)(9) relating to Exchange Act rule 18a–2;

(K) The requirements of Exchange Act rule 18a–5(a)(10) and (b)(8), provided that the Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 21(1)(d), 35; CRD articles 88, 91(1), 91(8); MiFID articles 9(1) and 16(3); MFC articles L. 511–55 through L. 511–70, L. 511–89 through L. 511–103, and L. 533–25; and Internal Control Order articles 85, 86, 92, and 93;

(L) The requirements of Exchange Act rule 18a–5(a)(12), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of CRR articles 103, 105(3) and 105(10); MiFID Org Reg. articles 72, 74 and 75; CRD article 73; MiFID Delegated Directive article 2; MFC article L. 511–41–1B; Decree of 6 September 2017 article 3; and AMF General Regulation article 312–6;

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rule 18a–3 pursuant to this Order;

(M) The requirements of Exchange Act rule 18a–5(a)(17) and (b)(13), as applicable, regarding one or more provisions of Exchange Act rules 15Fh–3 or 15Fk–1 for which substituted compliance is available under this Order, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 72, 73, and Annex I; MiFID articles 16(6) and 25(2); MLD articles 11 and 13; EMIR article 39(5); and MFC article L. 533–10 II, L. 533–13, L. 561–4–1, L. 561–5, L. 561–5–1, L. 561–6, R. 561–5, R. 561–5–1, R. 561–5–2, R. 561–5–3, R. 561–7, R. 561–10 II, R. 561–10–3, R. 561–11–1, R. 561–12, R. 561–15, R. 561–16, R. 561–18, and R. 561–19, in each case with respect to the relevant security-based swap or activity;

(*2*) With respect to the portion of Exchange Act rule 18a–5(a)(17) and (b)(13) that relates to Exchange Act rule 15Fh–3, the Covered Entity applies substituted compliance for such business conduct standard(s) of Exchange Act rule 15Fh–3 pursuant to this Order, as applicable, with respect to the relevant security-based swap or activity; and

(*3*) With respect to the portion of Exchange Act rule 18a–5(a)(17) and (b)(13) that relates to Exchange Act rule 15Fk–1, the Covered Entity applies substituted compliance for Exchange

Act section 15F(k) and Exchange Act rule 15Fk–1 pursuant to this Order;

(N) The requirements of Exchange Act rule 18a–5(a)(18)(i) and (ii) or (b)(14)(i) and (ii), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 11(1)(b) and EMIR RTS article 15(1)(a); and

(*2*) The Covered Entity applies substituted compliance for Exchange Act rule 15Fi–3 pursuant to this Order; and

(O) The requirements of Exchange Act rule 18a–5(a)(18)(iii) or (b)(14)(iii), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 11(1)(b) and EMIR RTS article 15(1)(a), in each case with respect to such security-based swap portfolio(s); and

(*2*) The Covered Entity applies substituted compliance for Exchange Act rule 15Fi–4 pursuant to this Order.

(ii) Paragraph (f)(1)(i) is subject to the following further conditions:

(A) Paragraphs (f)(1)(i)(A) through (D) and (H) are subject to the condition that the Covered Entity preserves all of the data elements necessary to create the records required by the applicable Exchange Act rules cited in such paragraphs and upon request furnishes promptly to representatives of the Commission the records required by those rules;

(B) A Covered Entity may apply the substituted compliance determination in paragraph (f)(1)(i)(M) to records of compliance with Exchange Act rule 15Fh–3(b), (c), (e), (f) and (g) in respect of one or more security-based swaps or activities related to security-based swaps; and

(C) This Order does not extend to the requirements of Exchange Act rule 18a–5(a)(13), (a)(14), (a)(16), (b)(9), (b)(10) or (b)(12).

(2)(i) *Preserve certain records.* The requirements of the following provisions of Exchange Act rule 18a–6, provided that the Covered Entity complies with the relevant conditions in this paragraph (f)(2)(i) and with the applicable conditions in paragraph (f)(2)(ii):

(A) The requirements of Exchange Act rule 18a–6(a)(1) or (a)(2), as applicable, provided that the Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 72, 74, 75, and Annex IV; CRR article 103; MiFIR article 25(1); EMIR article 9(2); MiFID articles 16(6) and 69(2); CRD article 73; MiFID Delegated Directive article 2; MFC articles L. 511–41–1B; L. 533–10 II, L. 621–8–4, L. 621–9, and L. 621–10; Decree of 6 September 2017 article 3; and AMF General Regulation article 312–6;

(B) The requirements of Exchange Act rule 18a–6(b)(1)(i) or (b)(2)(i), as applicable, provided that the Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 72, 74, 75, and Annex IV; CRR article 103; MiFIR article 25(1); EMIR article 9(2); MiFID articles 16(6) and 69(2); CRD article 73; MiFID Delegated Directive article 2; MFC articles L. 511–41–1B; L. 533–10 II, L. 621–8–4, L. 621–9, and L. 621–10; Decree of 6 September 2017 article 3; and AMF General Regulation article 312–6;

(C) The requirements of Exchange Act rule 18a–6(b)(1)(ii) and (iii), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 72, 74, and 75; EMIR article 9(2); CRD article 73; MiFID Delegated Directive article 2; MiFID 16(6); MFC article L. 511–41–1–B, L. 511–51 through L. 511–88, L. 533–2–2, and L. 533–10 II; Decree of 6 September 2017 article 3; AMF General Regulation article 312–6; Ministerial Order on the Supervisory Review and Evaluation Process; and Internal Control Order articles 85, 86, 92, and 93; and

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(D) The requirements of Exchange Act rule 18a–6(b)(1)(iv) or (b)(2)(ii), as applicable, provided that the Covered Entity is subject to and complies with the requirements of CRR article 103; MiFID Org Reg articles 72, 73, 74, 75, 76, Annex I and Annex IV; MiFIR article 25(1); EMIR article 9(2); CRD article 73; MiFID articles 16(6), 16(7); MiFID Delegated Directive article 2; MFC articles L. 511–41–1–B, L. 511–51 to L. 511–88, L. 533–2–2, L. 533–10 II, L. 533–10 III, Internal Control Order articles 85, 86, 92, and 93; Ministerial Order on the Supervisory Review and Evaluation Process; Decree of 6 September 2017 article 3; and AMF General Regulation article 312–6;

(E) The requirements of Exchange Act rule 18a–6(b)(1)(v), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 9(2); CRR articles 99, 294, 394, 415, 430 and Part Six: Title II and Title III; CRR Reporting ITS article 14 and annexes I–V and VIII–XIII; MiFID Org Reg article 72(1); and Internal Control Order articles 85, 86, 92, and 93;

(*2*) With respect to the requirements of Exchange Act rule 18a–6(b)(1)(v), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant this Order; and

(*3*) This Order does not extend to the requirements of Exchange Act rule 18a–6(b)(1)(v) relating to Exchange Act rule 18a–2;

(F) The requirements of Exchange Act rule 18a–6(b)(1)(vi) or (b)(2)(iii), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 9(2); MiFID Org Reg articles 72(1) and 73; MiFID article 16(6); and MFC articles L. 533–10 II, L. 561–12; and

(*2*) With respect to the requirements of Exchange Act rule 18a–6(b)(1)(vi), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(G) The requirements of Exchange Act rule 18a–6(b)(1)(vii) or (b)(2)(iv), as applicable, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 72(1) and 73; MiFIR article 25(1); EMIR article 9(2); MiFID article 16(6); and MFC article L. 533–10 II; and

(*2*) With respect to the requirements of Exchange Act rule 18a–6(b)(1)(vii), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(H) The requirements of Exchange Act rule 18a–6(b)(1)(viii), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of CRR articles 99, 294, 394, 415, 430 and Part Six: Title II and Title III; CRR Reporting ITS article 14 and annexes I–V and VIII–XIII, as applicable; MiFID Org Reg article 72(1); and Internal Control Order articles 85, 86, 92, and 93;

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act rule 18a–7(a)(1), (b), (c) through (h), and Exchange Act rule 18a–7(j) as applied to these requirements pursuant to this Order;

(*3*) With respect to the requirements of Exchange Act rule 18a–6(b)(1)(viii), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(*4*) This Order does not extend to the requirements of Exchange Act rule 18a–6(b)(1)(viii)(L); and

(*5*) This Order does not extend to the requirements of Exchange Act rule 18a–

6(b)(1)(viii)(M) relating to Exchange Act rule 18a–2.

(I) The requirements of Exchange Act rule 18a–6(b)(1)(ix), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 22(3)(c), 23, 24, 25(2), 26, 29(2)(c), 35 and 72(1); CRR articles 176, 286 and 293(1)(d); EMIR RTS; EMIR article 9(2); MiFID articles 16(2), 16(3), 16(5), 24(9); MiFID Delegated Directive article 11; CRD article 73, 75–87; MFC articles L. 511–41–1–B, L. 511–51 through L. 511–88, L. 533–10 I and II, L. 533–2, L. 533–2–2, and L. 533–12–4; AMF General Regulation articles 314–16, 314–17; Ministerial Order on the Supervisory Review and Evaluation Process; and Internal Control Order articles 94 through 96 and 99 through 102; and

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(J) The requirements of Exchange Act rule 18a–6(b)(1)(x), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 9(2); MiFID Org Reg article 72(1); CRD article 73; MiFID article 16(6); MFC articles L. 511–41–1–B, L. 511–51 through L. 511–88, L. 533–2–2, L. 533–10 II; Ministerial Order on the Supervisory Review and Evaluation Process; and Internal Control Order articles 94 through 96 and 99 through 102; and

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(K) The requirements of Exchange Act rule 18a–6(b)(1)(xii) or (b)(2)(vii), as applicable, regarding one or more provisions of Exchange Act rules 15Fh–3 or 15Fk–1 for which substituted compliance is available under this Order, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 9(2); MLD articles 11 and 13; MiFID Org Reg article 72(1); MiFID article 16(6); and MFC articles L. 533–10 II, L. 561–4–1, L. 561–5, L. 561–5–1, L. 561–6, R. 561–5, R. 561–5–1, R. 561–5–2, R. 561–5–3, R. 561–7, R. 561–10 II, R. 561–10–3, R. 561–11–1, R. 561–12, R. 561–15, R. 561–16, R. 561–18, R. 561–19, in each case with respect to the relevant security-based swap or activity;

(*2*) With respect to the portion of Exchange Act rule 18a–6(b)(1)(xii) or (b)(2)(vii) that relates to Exchange Act rule 15Fh–3, the Covered Entity applies substituted compliance for such business conduct standard(s) of Exchange Act rule 15Fh–3 pursuant to this Order, as applicable, with respect to the relevant security-based swap or activity; and

(*3*) With respect to the portion of Exchange Act rule 18a–6(b)(1)(xii) or (b)(2)(vii), as applicable, that relates to Exchange Act rule 15Fk–1, the Covered Entity applies substituted compliance for Exchange Act section 15F(k) and Exchange Act rule 15Fk–1 pursuant to this Order;

(L) The requirements of Exchange Act rule 18a–6(c), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 21(1)(f) and 72(1); MiFID article 16(6); and MFC article L. 533–10 II; and

(*2*) This Order does not extend to the requirements of Exchange act rule 18a–6(c) relating to Forms SBSE, SBSE–A, SBSE–C, SBSE–W, all amendments to these forms, and all other licenses or other documentation showing the registration of the Covered Entity with any securities regulatory authority or the U.S. Commodity Futures Trading Commission;

(M) The requirements of Exchange Act rule 18a–6(d)(1), provided that the Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 35 and 72(1); CRD articles 88, 91(1), 91(8); MiFID article 9(1), 16(3), 16(6); and MFC articles L. 511–55 through L. 511–70, L. 511–89 through L. 511–103, L. 533–10 II, L. 533–25;

(N) The requirements of Exchange Act rule 18a–6(d)(2), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 9(2); MiFID Org Reg articles 72(1) and 72(3); MiFID article 16(6); and MFC article L. 533–10 II; and

(*2*) With respect to the requirements of Exchange Act rule 18a–6(d)(2)(i), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(O) The requirements of Exchange Act rule 18a–6(d)(3), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 21(1)(f), 72, 73, and Annex I; MiFID article 16(6); and MFC article L. 533–10 II; and

(*2*) With respect to the requirements of Exchange Act rule 18a–6(d)(3)(i), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(P) The requirements of Exchange Act rule 18a–6(d)(4) and (d)(5), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 9(2); MiFID Org Reg articles 24, 25(2), 72(1) and 73; MiFID articles 16(2), 16(6), and 25(5); and MFC articles L. 533–10, L. 533–14; and

(*2*) The Covered Entity applies substituted compliance for Exchange Act rules 15Fi–3, 15Fi–4, and 15Fi–5 pursuant to this Order;

(Q) The requirements of Exchange Act rule 18a–6(e), provided that the Covered Entity is subject to and complies with the requirements of MiFID Org Reg articles 21(2), 58, 72(1) and 72(3); MiFID articles 16(5), 16(6); and MFC articles L. 533–2, L. 533–10 II; and

(R) The requirements of Exchange Act rule 18a–6(f), provided that the Covered Entity is subject to and complies with the requirements of MiFID Org Reg article 31(1); MiFID article 16(5); and MFC articles L. 533–2 and L. 533–10 II.

(ii) Paragraph (f)(2)(i) is subject to the following further conditions:

(A) A Covered Entity may apply the substituted compliance determination in paragraph (f)(2)(i)(K) to records related to Exchange Act rule 15Fh–3(b), (c), (e), (f) and (g) in respect of one or more security-based swaps or activities related to security-based swaps; and

(B) This Order does not extend to the requirements of Exchange Act rule 18a–6(b)(1)(xi), (b)(1)(xiii), (b)(2)(v), (b)(2)(vi), or (b)(2)(viii).

(3) *File Reports.* The requirements of the following provisions of Exchange Act rule 18a–7, provided that the Covered Entity complies with the relevant conditions in this paragraph (f)(3):

(i) The requirements of Exchange Act rule 18a–7(a)(1) or (a)(2), as applicable, and the requirements of Exchange Act rule 18a–7(j) as applied to the requirements of Exchange Act rule 18a–7(a)(1) or (a)(2), as applicable, provided that:

(A) The Covered Entity is subject to and complies with the requirements of CRR articles 99, 394, 430 and Part Six: Title II and Title III; CRR Reporting ITS annexes I, II, III, IV, V, VIII, IX, X, XI, XII and XIII, as applicable;

(B) The Covered Entity files periodic unaudited financial and operational information with the Commission or its designee in the manner and format required by Commission rule or order and presents the financial information in the filing in accordance with generally accepted accounting principles that the Covered Entity uses to prepare general purpose publicly

available or available to be issued financial statements in France;

(C) With respect to the requirements of Exchange Act rule 18a–7(a)(1), the Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order; and

(D) With respect to the requirements of Exchange Act rule 18a–7(a)(1), the Covered Entity applies substituted compliance for the requirements of Exchange Act rule 18a–6(b)(1)(viii) pursuant to this Order;

(ii) The requirements of Exchange Act rule 18a–7(a)(3) and the requirements of Exchange Act rule 18a–7(j) as applied to the requirements of paragraph (a)(3) of Exchange Act rule 18a–7, provided that:

(A) The Covered Entity is subject to and complies with the requirements of CRR articles 99, 394, 431, 433, 452, 454, and 455; CRR Reporting ITS annexes I, II, VIII and IX, as applicable; and

(B) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(iii) The requirements of Exchange Act rule 18a–7(b), provided that:

(A) The Covered Entity is subject to and complies with the requirements of CRR articles 431 through 455; MFC articles L. 511–35, L. 511–36, L. 511–37, R. 511–6; and French Commerce Code articles L. 232–1, R. 232–1 through R. 232–8, L. 823–1 through L. 823–8–1; and

(B) The Covered Entity applies substituted compliance for the requirements of Exchange Act rule 18a–6(b)(1)(viii) pursuant to this Order.

(iv) The requirements of Exchange Act rule 18a–7(c), (d), (e), (f), (g) and (h) and the requirements of Exchange Act rule 18a–7(j) as applied to the requirements of paragraphs (c), (d), (e), (f), (g) and (h) of Exchange Act rule 18a–7, provided that:

(A) The Covered Entity is subject to and complies with the requirements of CRR articles 26(2), 132(5), 154, 191, 321, 325bi, 350, 353, 368, 418; MFC articles L. 511–35, L. 511–36, L. 511–37, L. 511–38 or article L. 533–5, as applicable; MFC articles R. 511–6, L. 511–45, and L. 533–10 II; French Commerce Code articles L. 232–1, R. 232–1 through R. 232–8, L. 823–1 through L. 823–8–1; Decree of 6 September 2017 articles 3 and 10; and AMF General Regulation articles 312–6 and 312–7;

(B) With respect to financial statements, the Covered Entity is required to file annually with the French AMF, including a report of an independent public accountant covering the financial statements, the Covered Entity:

(*1*) Simultaneously sends a copy of such annual financial statements and the report of the independent public accountant covering the annual financial statements to the Commission in the manner specified on the Commission's website;

(*2*) Includes with the transmission the contact information of an individual who can provide further information about the financial statements and report;

(*3*) Includes with the transmission the report of an independent public accountant required by Exchange Act rule 18a–7(c)(1)(i)(C) covering the annual financial statements if French laws do not require the Covered Entity to engage an independent public accountant to prepare a report covering the annual financial statements; provided, however, that such report of the independent public accountant may be prepared in accordance with generally accepted auditing standards in France that the independent public accountant uses to perform audit and attestation services and the accountant complies with French independence requirements;

(*4*) Includes with the transmission the reports required by Exchange Act rule 18a–7(c)(1)(i)(B) and (C) addressing the statements identified in Exchange Act rule 18a–7(c)(3) or (c)(4), as applicable, that relate to Exchange Act rule 18a–4; provided, however, that the report of the independent public accountant required by Exchange Act rule 18a–7(c)(1)(i)(C) may be prepared in accordance with generally accepted auditing standards in France that the independent public accountant uses to perform audit and attestation services and the accountant complies with French independence requirements;

(*5*) Includes with the transmission the supporting schedules and reconciliations, as applicable, required by Exchange Act rules 18a–7(c)(2)(ii) and (iii), respectively, relating to Exchange Act rule 18a–2; and

(*6*) Includes with the transmission the supporting schedules and reconciliations, as applicable, required by Exchange Act rules 18a–7(c)(2)(ii) and (iii), respectively, relating to Exchange Act rules 18a–4 and 18a–4a;

(C) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order; and

(D) The Covered Entity applies substituted compliance for the requirements of Exchange Act rule 18a–6(b)(1)(viii) pursuant to this Order.

(4)(i) *Provide Notification.* The requirements of the following provisions of Exchange Act rule 18a–8, provided that the Covered Entity complies with the relevant conditions in this paragraph (f)(4)(i) and with the applicable conditions in paragraph (f)(4)(ii):

(A) The requirements of paragraphs (a)(1)(i), (a)(1)(ii), (b)(1), (b)(2), and (b)(4) of Exchange Act rule 18a–8 and the requirements of Exchange Act rule 18a–8(h) as applied to the requirements of paragraphs (a)(1)(i), (a)(1)(ii), (b)(1), (b)(2), and (b)(4) of Exchange Act rule 18a–8, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of CRR article 366(5); MFC articles L. 511–33II, L. 634–1, and L. 634–2; and Internal Control Order article 249 and 249–1; and

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(B) The requirements of Exchange Act rule 18a–8(c) and the requirements of Exchange Act rule 18a–8(h) as applied to the requirements of Exchange Act rule 18a–8(c), provided that the Covered Entity is subject to and complies with the requirements of MFC articles L. 511–33II, L. 634–1, and L. 634–2; and Internal Control Order article 249 and 249–1.

(C) The requirements of Exchange Act rule 18a–8(d) and the requirements of Exchange Act rule 18a–8(h) as applied to the requirements of Exchange Act rule 18a–8(d), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MFC articles L. 511–33II, L. 634–1, and L. 634–2; and Internal Control Order article 249 and 249–1; and

(*2*) This Order does not extend to the requirements of Exchange Act rule 18a–8(d) to give notice with respect to books and records required by Exchange Act rule 18a–5 for which the Covered Entity does not apply substituted compliance pursuant to this Order;

(D) The requirements of Exchange Act rule 18a–8(e) and the requirements of Exchange Act rule 18a–8(h) as applied to the requirements of Exchange Act rule 18a–8(e), provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of MFC articles L. 511–33II, L. 634–1, and L. 634–2; and Internal Control Order article 249 and 249–1;

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section

15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order;

(*3*) This Order does not extend to the requirements of Exchange act rule 18a–8(e) relating to Exchange Act rule 18a–2 or to the requirements of Exchange Act rule 18a–8(h) as applied to the requirements of Exchange Act rule 18a–8(e) relating to Exchange Act rule 18a–2; and

(*4*) This Order does not extend to the requirements of Exchange act rule 18a–8(e) relating to Exchange Act rule 18a–4 or to the requirements of Exchange Act rule 18a–8(h) as applied to the requirements of Exchange Act rule 18a–8(e) relating to Exchange Act rule 18a–4;

(ii) Paragraph (f)(4)(i) is subject to the following further conditions:

(A) The Covered Entity:

(*1*) Simultaneously sends a copy of any notice required to be sent by French law cited in this paragraph of the Order to the Commission in the manner specified on the Commission's website; and

(*2*) Includes with the transmission the contact information of an individual who can provide further information about the matter that is the subject of the notice;

(B) This Order does not extend to the requirements of paragraphs (a)(2) and (b)(3) of Exchange Act rule 18a–8 relating to Exchange Act rule 18a–2 or to the requirements of Exchange Act rule 18a–8(h) as applied to the requirements of paragraphs (a)(2) and (b)(3) of Exchange Act rule 18a–8 relating to Exchange Act rule 18a–2; and

(C) This Order does not extend to the requirements of paragraph (g) of Exchange Act rule 18a–8 or to the requirements of Exchange Act rule 18a–8(h) as applied to the requirements of paragraph (g) of Exchange Act rule 18a–8.

(5) *Securities Counts.* The requirements of Exchange Act rule 18a–9, provided that:

(*1*) The Covered Entity is subject to and complies with the requirements of EMIR article 11(1)(b); EMIR RTS articles 12 and 13; MiFID Delegated Directive articles 2 and 8; Decree of 6 September 2017 articles 3 and 10; and AMF General Regulation articles 312–6 and 312–7; and

(*2*) The Covered Entity applies substituted compliance for the requirements of Exchange Act section 15F(e) and Exchange Act rules 18a–1 through 18a–1d pursuant to this Order.

(6) *Daily Trading Records.* The requirements of Exchange Act section 15F(g), provided that the Covered Entity is subject to and complies with the requirements of MFC articles L. 533–10 II and L. 533–10 III; and MiFID Org Reg article 21(1)(f), 21(4), and 72(1).

(7) *Examination and Production of Records.* Notwithstanding the forgoing provisions of paragraph (f) of this Order, this Order does not extend to, and Covered Entities remain subject to, the requirement of Exchange Act section 15F(f) to keep books and records open to inspection by any representative of the Commission and the requirement of Exchange Act rule 18a–6(g) to furnish promptly to a representative of the Commission legible, true, complete, and current copies of those records of the Covered Entity that are required to be preserved under Exchange Act rule 18a–6, or any other records of the Covered Entity that are subject to examination or required to be made or maintained pursuant to Exchange Act section 15F that are requested by a representative of the Commission.

(8) *English Translations.* Notwithstanding the forgoing provisions of paragraph (f) of this Order, to the extent documents are not prepared in the English language, Covered Entities must promptly furnish to a representative of the Commission upon request an English translation of any record, report, or notification of the Covered Entity that is required to be made, preserved, filed, or subject to examination pursuant to Exchange Act section 15F of this Order.

(g) Definitions

(1) ''Covered Entity'' means an entity that:

(i) Is a security-based swap dealer or major security-based swap participant registered with the Commission;

(ii) Is not a ''U.S. person,'' as that term is defined in rule 3a71–3(a)(4) under the Exchange Act; and

(iii) Is an investment firm authorized by the ACPR to provide investment services or perform investment activities in the French Republic, or a credit institution authorized by the ACPR, after approval by the AMF of its program of operations, to provide investment services or perform investment activities in the French Republic, and supervised by the AMF under its Tier 1 framework.

(2) ''MiFID'' means the ''Markets in Financial Instruments Directive,'' Directive 2014/65/EU, as amended from time to time.

(3) ''MFC'' means France's ''Code monétaire et financier,'' as amended from time to time.

(4) ''Internal Control Order'' means the French AMF's Arrêté of 3 November 2014 on Internal Control of Companies in the Banking, Payment Services and Investment Services Sector Subject to the Supervision of the Authorité de Contrôle Prudentiel et de Résolution, as amended from time to time.

(5) ''Prudential Supervision and Risk Assessment Order'' means the French ministerial order on prudential supervision and risk assessment, as amended from time to time.

(6) ''MiFID Org Reg'' means Commission Delegated Regulation (EU) 2017/565, as amended from time to time.

(5) ''MiFID Delegated Directive'' means Commission Delegated Directive (EU) 2017/593, as amended from time to time.

(6) ''MLD'' means Directive (EU) 2015/849, as amended from time to time.

(7) ''MiFIR'' means Regulation (EU) 600/2014, as amended from time to time.

(8) ''EMIR'' means the ''European Market Infrastructure Regulation,'' Regulation (EU) 648/2012, as amended from time to time.

(9) ''EMIR RTS'' means Commission Delegated Regulation (EU) 149/2013, as amended from time to time.

(10) ''EMIR Margin RTS'' means Commission Delegated Regulation (EU) 2016/2251, as amended from time to time.

(11) ''CRR Reporting ITS'' means Commission Implementing Regulation (EU) 680/2014, as amended from time to time.

(12) ''CRD'' means Directive 2013/36/EU, as amended from time to time.

(13) ''CRR'' means Regulation (EU) 575/2013, as amended from time to time.

(14) ''MAR'' means the ''Market Abuse Regulation,'' Regulation (EU) 596/2014, as amended from time to time.

(15) ''MAR Investment Recommendations Regulation'' means Commission Delegated Regulation (EU) 2016/958, as amended from time to time.

(16) ''AMF'' means the French Autorité des Marchés Financiers.

(17) ''ACPR'' means the French Authorité de Contrôle Prudentiel et de Résolution.

(18) ''ECB'' means the European Central Bank.

(19) ''Accounting Directive'' means Directive 2013/34/EU of the European Parliament and of the Council of 26 June 2013, as amended from time to time.

(20) ''Decree of 6 September 2017'' means France's Decree number 2017–1324 of 6 September 2017, as amended from time to time.

(21) ''AMF General Regulation'' means France's ''Règlement Général de L'Autorité des Marchés Financiers,'' as amended from time to time.

(22) ''Ministerial Order on the Supervisory Review and Evaluation Process'' means France's Arrêté of 3 November 2014 on the Process for Prudential Supervision and Risk Assessment of Banking Service Providers and Investment Firms Other than Portfolio Management Companies, as amended from time to time.

(23) ''French Commerce Code'' means the French Commercial Code, as amended from time to time.

(24) ''Prudentially regulated'' means a Covered Entity that has a ''prudential regulator'' as that term is defined in Exchange Act section 3(a)(74).

(25) ''Decree of 3 November 2014 relating to capital buffers'' means Arrêté of 3 November 2014 relating to the capital buffers of banking service providers and investment firms other than portfolio management companies, as amended from time to time.

(26) ''BRRD'' means Bank Recovery and Resolution Directive 2014/59/EU of the European Parliament and of the Council of 15 May 2014, as amended from time to time.

(27) ''Decree of 20 February 2007 relating to prudential requirements'' means Arrêté of 20 February 2007 relating to prudential requirements applicable to credit institutions and investment firms, as amended from time to time.

By the Commission.

Vanessa A. Countryman,

Secretary.

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Part IV

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 226

Endangered and Threatened Wildlife and Plants; Revision of Critical Habitat for the Southern Resident Killer Whale Distinct Population Segment; Final Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 226

[Docket No. 210719–0149]

RIN 0648–BH95

Endangered and Threatened Wildlife and Plants; Revision of Critical Habitat for the Southern Resident Killer Whale Distinct Population Segment

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

ACTION: Final rule.

SUMMARY: We, NMFS, issue a final rule to revise the critical habitat designation for the Southern Resident killer whale (*Orcinus orca*) distinct population segment (DPS) under the Endangered Species Act (ESA) by designating six additional coastal critical habitat areas along the U.S. West Coast. Specific newly designated areas along the U.S. West Coast include 15,910 square miles (mi^2) (41,207 square kilometers (km^2)) of marine waters between the 20-feet (ft) (6.1-meter (m)) depth contour and the 656.2-ft (200-m) depth contour from the U.S. international border with Canada south to Point Sur, California. We have excluded one area, the Quinault Range Site (including a 10-km buffer around a portion of the site), comprising 1,400.4 mi^2 (3627 km^2), from the critical habitat designation because we have determined that the benefits of exclusion outweigh the benefits of inclusion, and exclusion will not result in extinction of the species.

DATES: This rule is effective September 1, 2021.

ADDRESSES: The final rule, maps, and other supporting documents (Economic Report, ESA Section 4(b)(2) Report, and Biological Report) can be found on the NMFS website at *https://www.fisheries.noaa.gov/action/critical-habitat-southern-resident-killer-whale.*

FOR FURTHER INFORMATION CONTACT: Lynne Barre, NMFS West Coast Region, 206–526–4745; or Lisa Manning, NMFS, Office of Protected Resources, 301–427–8466.

SUPPLEMENTARY INFORMATION:

Background

NMFS listed the Southern Resident killer whale DPS as endangered under the ESA in 2005 (70 FR 69903; November 18, 2005). In 2006, NMFS designated critical habitat for the Southern Resident killer whale DPS in inland waters of Washington State (71 FR 69054; November 29, 2006). The designated critical habitat consists of three areas: (1) The Summer Core Area in Haro Strait and waters around the San Juan Islands, (2) Puget Sound Area, and (3) the Strait of Juan de Fuca Area. Together, these areas comprise approximately 2,560 mi^2 (6,630 km^2) of marine habitat.

The 2006 final rule designating critical habitat identified three habitat features essential to the conservation of the DPS: (1) Water quality to support growth and development; (2) prey species of sufficient quantity, quality, and availability to support individual growth, reproduction, and development, as well as overall population growth; and (3) passage conditions to allow for migration, resting, and foraging.

On January 21, 2014, we received a petition from the Center for Biological Diversity (CBD) requesting revisions to the critical habitat designation for the Southern Resident killer whale DPS. CBD requested we revise critical habitat to include ''inhabited marine waters along the West Coast of the United States that constitute essential foraging and wintering areas,'' specifically the region between Cape Flattery, Washington, and Point Reyes, California, extending from the coast to a distance of 47.2 mi (76 km) offshore.

On April 25, 2014, we announced in our 90-day finding that the petition presented substantial scientific information indicating that a revision to the current critical habitat designation may be warranted and requested public comments (79 FR 22933). Due to new information available regarding habitat use by Southern Resident killer whales, we decided a revision to critical habitat was warranted, and we announced our intention to proceed toward a proposed rule in the 12-month finding (80 FR 9682; February 24, 2015).

CBD filed a complaint in August 2018 with the U. S. District Court for the Western District of Washington at Seattle seeking an order from the Court establishing deadlines for NMFS to revise the Southern Resident killer whale critical habitat designation. A court-approved settlement agreement was filed on April 17, 2019 (*Center for Biological Diversity* v. *National Marine Fisheries Service,* 2:18–cv–01201–RSM (W.D. Wash.)). The settlement agreement stipulated that NMFS must submit a proposed rule revising critical habitat to the Office of the Federal Register by September 6, 2019.

Based on the recommendations provided in the Draft Biological Report, the Initial Regulatory Flexibility Analysis (IRFA) and ESA section 4(b)(2) analysis (which considers exclusions to critical habitat based on economic, national security and other relevant impacts), we published a proposed rule on September 19, 2019 (84 FR 49214), to designate marine waters between the 20-ft (6.1-m) depth contour and the 656.2-ft (200-m) depth contour from the U.S. international border with Canada south to Point Sur, California, as Southern Resident killer whale critical habitat. In accordance with the definition of critical habitat under the ESA, this area contained physical or biological features essential to the conservation of the species and which may require special management considerations or protections. The proposed rule included background information on Southern Resident killer whale biology and habitat use. That background information is not included here but can be accessed by referring to the proposed rule (84 FR 49214; September 19, 2019) and supporting documents (at *https://www.fisheries.noaa.gov/west-coast/endangered-species-conservation/critical-habitat-southern-resident-killer-whales*).

In the proposed rule, we described the physical or biological features essential to the conservation of Southern Resident killer whales as (1) water quality to support growth and development; (2) prey species of sufficient quantity, quality, and availability to support individual growth, reproduction, and development, as well as overall population growth; and (3) passage conditions to allow for migration, resting, and foraging. We requested public comments through December 18, 2019, and held three public hearings. For a complete description of our proposed action, we refer the reader to the proposed rule (84 FR 49214; September 19, 2019). The proposed rule and supporting documents included information on the natural history of Southern Resident killer whales, which has been updated in the Final Biological Report (NMFS 2021a).

Statutory and Regulatory Background for Critical Habitat Designations

The ESA defines critical habitat under section 3(5)(A) as the (1) specific areas within the geographical area occupied by the species at the time it is listed, on which are found those physical or biological features essential to the conservation of the species and which may require special management considerations or protection; and (2) specific areas outside the geographical area occupied by the species at the time it is listed, upon a determination by the

Secretary of Commerce (Secretary) that such areas are essential for the conservation of the species (16 U.S.C. 1532(5)(A)). Conservation is defined in section 3(3) of the ESA as to use, and the use of, all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this Act are no longer necessary (16 U.S.C. 1532(3)). Section 3(5)(C) of the ESA provides that, except in those circumstances determined by the Secretary, critical habitat shall not include the entire geographical area which can be occupied by the threatened or endangered species. Our regulations provide that critical habitat shall not be designated within foreign countries or in other areas outside U.S. jurisdiction (50 CFR 424.12(g)).

Section 4(a)(3)(B) prohibits designating as critical habitat any lands or other geographical areas owned or controlled by the Department of Defense (DOD) or designated for its use, that are subject to an Integrated Natural Resources Management Plan (INRMP) prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary determines in writing that such plan provides a benefit to the species for which critical habitat is designated.

Section 4(b)(2) of the ESA requires us to designate critical habitat for threatened and endangered species on the basis of the best scientific data available and after taking into consideration the economic impact, the impact on national security, and any other relevant impact, of specifying any particular area as critical habitat. Pursuant to this section, the Secretary may exclude any area from critical habitat upon determining that the benefits of such exclusion outweigh the benefits of specifying such area as part of the critical habitat. However, the Secretary may not exclude areas if this will result in the extinction of the species.

Once critical habitat is designated, section 7(a)(2) of the ESA requires Federal agencies to ensure that actions they fund, authorize, or carry out are not likely to destroy or adversely modify that habitat (16 U.S.C. 1536(a)(2)). This requirement is in addition to the section 7(a)(2) requirement that Federal agencies ensure their actions are not likely to jeopardize the continued existence of ESA-listed species. Specifying the geographic location of critical habitat also facilitates implementation of section 7(a)(1) of the ESA by identifying areas where Federal agencies can focus their conservation programs and use their authorities to further the purposes of the ESA. Critical habitat requirements do not apply to citizens engaged in actions on private land that do not involve a Federal agency. However, designating critical habitat can help focus the efforts of other conservation partners (*e.g.,* state and local governments, individuals, and non-governmental organizations).

Summary of Changes From the Proposed Rule

We evaluated the comments and information received from the public during the public comment period and at public hearings. Based on our consideration of these comments and information and our reconsideration of issues discussed in the proposed rule, the final rule and supporting documents include one substantive change to the exclusions for national security impacts, as well as inclusion of clarifications and new information and references in response to public comments. Below we briefly summarize these changes and clarifications, which are discussed in further detail in the relevant responses to comments and other sections of this final rule.

After considering public comments received and the best scientific information available, the final rule reduces the extent of the excluded 10-km buffer around the Quinault Range Site (QRS) where the QRS overlaps with the Olympic Coast National Marine Sanctuary (OCNMS).

In accordance with section 4(b)(2) of the ESA, our proposed rule excluded the QRS based on national security impacts. It also excluded a 10-km buffer around the site, calculated by the Navy based on the full extent to which noise-related impacts on fish species are estimated to occur from the use of the largest explosives the Navy foresees testing within the QRS. We received numerous public comments opposing the exclusion and one comment pointing out that part of the QRS overlaps with the OCNMS.

After considering these comments and requesting additional information from the Navy regarding planned activities in the OCNMS, we have reduced the extent of the 10-km buffer being excluded, where the QRS overlaps with the OCNMS. As detailed in the Section 4(b)(2) Report (NMFS 2021b), we found the benefits of designating critical habitat for Southern Resident killer whales within this portion of the buffer are not outweighed by national security impacts of including that portion. This change represents a reduction in the size of the area being excluded from critical habitat compared to the proposed rule. The proposed exclusion area encompassed approximately 1,687.9 mi^2 (4,371.5 km^2) of potential critical habitat, and the final exclusion area encompasses 1,400.4 mi^2 (3627 km^2) of potential critical habitat.

In addition to the one substantive change in the final rule, we also updated our supporting documents with additional information and clarifications based on the public comments, including updates related to sound, inclusion of newly available references, and clarifications related to our economic analysis. A number of comments requested that we include sound as a fourth essential feature or more explicitly describe how communication space is encompassed within the prey and passage essential features. After carefully considering the studies cited by commenters seeking to include sound as a fourth essential feature, we are still not able to identify specific in-water sound levels or thresholds for communication, behavioral or displacement impacts on Southern Resident killer whales (as requested by CBD) so we consider effects of sound qualitatively (see further explanation in section 'Physical and Biological Features Essential to Conservation' and in the Biological Report, NMFS 2021a, section V.B.4). Because potential impacts of sound are already addressed through qualitative section 7 analyses of the prey and passage features, as well as analyses of effects of sound on individual whales themselves, we have not included sound as a separate feature. However, in response to the concerns expressed in the comments, we have added more detail to the Final Biological Report (NMFS 2021a, sections V.B.2, V.B.3, and V.B.4) to clarify that the effects of anthropogenic noise on communication and social behavior are and will continue to be evaluated through the prey and passage essential features, as well as analyses of effects to individual whales. Activities producing sound that impact Southern Resident prey availability (including access to prey and impacts to communication for prey sharing) or safe and unrestricted passage (including passage necessary for social behavior) are considered activities that may require special management considerations under section 7 of the ESA. Finally, we also updated the Final Biological Report to include information on how this approach is compatible with the approaches used to address sound for other listed species: Cook Inlet beluga whale DPS, the Main Hawaiian Islands insular false killer whale DPS, and listed humpback whale

DPSs. Also, see the response to comment 8 regarding sound.

Multiple commenters provided information and citations for recent scientific studies not included in the proposed rule. In response, we have added to the Final Biological Report (NMFS 2021a) descriptions of and reference to multiple new studies that were published since the publication of the proposed critical habitat rule.

The Final Economic Analysis (FEA) in the Final Economic Report (IEc 2021) includes updates and clarifications from the draft version in response to public comments. Specifically, the analysis incorporates new information made available after development of the Draft Economic Analysis (DEA) on the Pacific Fishery Management Council (PFMC)'s ad-hoc Southern Resident Killer Whale Working Group, and publication of its Final Draft Risk Assessment for Salmon Fishery Management Plan (FMP) Impacts to Southern Resident Killer Whales (PFMC 2020). In response to public comment, the Sacramento District has been added to the list of United States Army Corps of Engineers (USACE) districts that manage activities that may be affected by the expansion (section 2.10, IEc 2021). The FEA (IEc 2021) also incorporates a Final Regulatory Flexibility Analysis (FRFA) and updates the timeframe and dollar year of the analysis to reflect the present schedule of the final rule. Therefore, differences in anticipated costs between the DEA and the FEA reflect an update to the timeframe of the analysis and the dollar year, as opposed to changes in the costs of consultation. No substantive changes were made between the IRFA and the Final Regulatory Flexibility Analysis (FRFA) as changes incorporated in the final rule do not affect the economic analysis and conclusions.

Summary of Comments and Responses

We solicited comments on the proposed designations and exclusions as well as the documents supporting the proposed rulemaking. To facilitate public participation, the proposed rule was made available on our website and comments were accepted via standard mail and through the Federal eRulemaking portal. We also solicited public comments at three public hearings, which were held on November 4, 2019, in Santa Cruz, CA; November 5, 2019, in Newport, OR; and November 6, 2019, in Seattle, WA. The public comment period closed on December 18, 2019.

We received 218 unique comments, including 180 in support, 22 opposed, and 16 that provided information and/or requested changes to the rule without stating support or opposition. We have considered all public comments, and provide responses to all substantive issues raised by commenters that are relevant to the proposed revision of Southern Resident killer whale critical habitat. We have not responded to comments or concerns outside the scope of this rulemaking. Comments were received from a range of sources including: Global and local environmental non-profit groups, fishing industry associations, local and state government, state agencies, other Federal agencies (*e.g.,* the Marine Mammal Commission, NOAA's National Ocean Service National Marine Sanctuaries Program, USACE), merchant shipping associations, trade associations, scientists and scientific groups, university students, elementary school students, educational groups, aquariums, legal groups, and individual citizens. The majority of individual concerned citizens were in support of the expanded critical habitat designation. The Marine Mammal Commission generally agreed with NMFS's determinations and supports the geographic boundaries we proposed.

Criteria for Designating Critical Habitat

Comment 1: One commenter felt that the revised critical habitat was not prudent, stating that it would not result in any new conservation measures or protections and, therefore, would not provide benefits to the species. The commenter referred to 16 U.S.C. 1533(a)(3) to argue that NMFS must demonstrate that designation of critical habitat designation is prudent, and cited 50 CFR 424.12(a)(1)(ii) (subsequently revised in 2019) to argue that designation is not prudent when it ''would not be beneficial to the species.''

Response: The ESA requires that NMFS designate critical habitat to the maximum extent prudent and determinable (16 U.S.C. 1533(a)(3)). Contrary to the interpretation of the commenter, it does not require that NMFS demonstrate prudence as a condition for designating critical habitat.

The proposed and final rules to revise critical habitat for Southern Resident killer whales follow previous ESA implementing regulations, as the most recent revisions to the implementing regulations, which became effective on September 26, 2019, only apply to classification and critical habitat rules for which a proposed rule was published after September 26, 2019 (see 84 FR 45020; August 27, 2019). The proposed rule for the revision to Southern Resident killer whale critical habitat (84 FR 49214) was published on September 19, 2019. With respect to critical habitat designations, the previous ESA implementing regulations at 50 CFR 424.12(a)(1)(ii) stated that a designation of critical habitat is not prudent when such a designation is not beneficial to the species. In determining if designation would not be beneficial, NMFS may consider, among other factors, whether the present or threatened destruction, modification, or curtailment of the habitat or range of a species is not a threat to the species, or if any areas meet the definition of critical habitat.

In general, ''not prudent'' determinations are uncommon, because most species are listed under ESA, at least in part, due to impacts to their habitat or curtailment of their range (see 81 FR 7413; February 11, 2016 response to Comment 61), and because there is an inherent benefit of critical habitat designation. Most ''not prudent'' findings are a result of a determination that designating habitat would increase harm or threats to the species, such as species highly prized for collection where identifying locations would render the species vulnerable to collection. Southern Residents killer whales were listed as endangered, in part, due to modification to their habitat from vessel traffic, contaminants, and changes to prey availability (see 70 FR 69903; November 18, 2005). If areas do not meet the definition of critical habitat, it is also permissible to not designate critical habitat; however, specific areas within the geographical area occupied by Southern Resident killer whales that we are designating, do meet the definition of critical habitat (*i.e.,* they contain the essential features and may require special management considerations or protection).

The commenter's statement that the proposed critical habitat would not result in any new conservation measures or protections refers to our findings in the DEA (IEc 2019) that there are no particular projects or activities for which NMFS considers it likely that section 7 consultation on coastal critical habitat for the killer whales would result in different conservation efforts than section 7 consultation without the revised critical habitat. However, this finding does not mean the critical habitat designation provides no benefits to the species. We find there are benefits and disagree with the commenter. First, although we do not consider additional conservation efforts from section 7 consultations to be likely, we cannot rule out that some modifications may result from section 7 consultations, and

such potential modifications would provide conservation value to the species. Secondly, although the direct benefit that the statute provides is through section 7 consultation, designating critical habitat may carry additional benefits to the species beyond the protections from section 7(a)(2) consultation. Specifically, these additional benefits, outlined in the Final ESA Section 4(b)(2) Report (NMFS 2021b), include facilitating implementation of section 7(a)(1) of the ESA by identifying areas where Federal agencies can focus their conservation programs and use their authorities to further the purposes of the ESA. Furthermore, other additional benefits include the generation of more detailed information about the status of Southern Resident killer whales, increasing education and awareness of parties involved in section 7 consultations and the public, which can lead to activities that benefit the killer whales or their habitat.

We continue to find that the expanded critical habitat is prudent.

Geographical Areas Occupied by the Species

Comment 2: We received several comments regarding the proposal to designate critical habitat in waters deeper than 20 ft (6.1 m) based on extreme high water. Some commenters felt that we should include waters shallower than 20 ft (6.1 m) because nearshore areas support killer whale prey, making them essential to the conservation of Southern Resident killer whales. The importance of these habitats for salmon and forage fish was the predominant argument by commenters for including shallow waters as critical habitat for Southern Resident killer whales.

Commenters generally acknowledged that many nearshore areas are outside the geographical area occupied by the species, but viewed them as essential for the conservation of the species because they provide critical habitat to the Southern Resident food chain, including juvenile salmon and their forage fish prey. Two commenters argued the unoccupied nearshore areas should be designated as critical habitat because they contain the essential feature of prey species (of sufficient quantity, quality and availability to support individual growth, reproduction and development, as well as overall population growth). One believed that limiting critical habitat to occupied areas is not adequate to ensure the conservation of the species, while another felt that designating these areas as critical habitat would help support salmon and killer whale resilience to climate change impacts. While most comments on this topic requested the inclusion of all nearshore areas in the critical habitat designation, a few requested the inclusion of just those nearshore, as well as estuarine, and freshwater areas associated with Chinook salmon rivers for stocks identified by NMFS and the Washington Department of Fish and Wildlife (WDFW) as priority stocks for Southern Resident killer whales.

One commenter argued that killer whales do occupy the waters shallower than 20 ft in depth, citing observational data from shore-based sightings of Southern Resident killer whales in the San Juan Islands foraging and socializing in shallow waters when transiting the area. The commenter argued that these waters are accessible to the killer whales at high tide, and that the shallow waters may constitute ''active space'' around individual whales in which they can interact with each other and their prey. They argued that nearshore waters should be designated as critical habitat because activities taking place in nearshore waters could adversely modify adjacent deeper waters within the proposed critical habitat. Lastly, for the purposes of regulatory simplicity, one commenter sought to align the critical habitat boundary with the high water line regulatory boundary used by the USACE.

Response: The final critical habitat designation is consistent with the proposed rule and does not include waters shallower than 20 ft (6.1 m) based on mean high water. Similar to the critical habitat for inland waters, there are little to no data to support that the whales use the shallow areas regularly, or could physically access some areas, even during high tide conditions.

The limited information providing new observations of Southern Resident killer whale use of shallow waters in the San Juan Islands we received is not sufficient to consider all shallow areas as occupied or essential to the conservation of Southern Resident killer whales. The observations provided represent rare occurrences and were located in inland waters rather than outer coastal waters. Also, based on data from four satellite-tagged Southern Resident killer whales, only less than 1 percent of the whales' outer coastal locations were in depths less than 6 m (Northwest Fisheries Science Center (NWFSC) unpubl. data, see the Biological Report, NMFS 2021a). Satellite-based locations are not exact, and we don't know the tidal conditions for these observations. We are not revising the inland waters critical habitat designation at this time, and neither the bathymetry of the San Juan Islands nearshore areas nor the unique observations of Southern Resident killer whales in these areas would be representative of outer coastal areas.

Regulatory alignment with USACE or other management boundaries is not a basis for designating critical habitat in unoccupied areas. Additionally, extreme high water data for delineating boundaries within geographic information system (GIS) software along the coast was not readily available for many locations. Therefore, similar to the proposed rule, we continue to use the 20-ft (6.1-m) depth relative to mean high water as the eastern boundary of coastal critical habitat.

Not designating waters shallower than 20 ft (6.1 m) (based on mean high water) as critical habitat does not preclude consultation on activities that occur in these shallow nearshore or inland freshwater areas. ESA section 7 requirements that Federal agencies ensure their actions are not likely to destroy or adversely modify critical habitat applies equally to actions occurring outside of designated critical habitat as to actions occurring within designated critical habitat. Furthermore, specific inland freshwater areas are designated as critical habitat for ESA-listed salmon runs (70 FR 52487; September 2, 2005 and 70 FR 52629; September 2, 2005), including certain priority Chinook runs (NMFS and WDFW 2018), and are, therefore, subject to section 7 consultations.

Specific Areas

Comment 3: Many commenters expressed support for the proposed geographic extent of the revised critical habitat in U.S. ocean waters from Cape Flattery, Washington, south to Point Sur, California. Two commenters felt that the coastwide designation of critical habitat was too broad, and sought to limit the spatial extent of the designation to areas of regular or consistent use. They disputed the southern and western boundaries and proposed alternative limitations to the boundaries of the specific areas, including by time and by the locations of primary essential features. Other commenters requested inclusion of additional areas because they felt the current proposed areas were not sufficient to conserve the whales.

One commenter referred to 16 U.S.C. 1532(5)(C), noting ESA directives that critical habitat not include the entire geographical area which can be occupied by the listed species, except in special circumstances. They referred to

the 1978 amendments to the ESA, stating that congressional intent was to curtail the practice of designating critical habitat throughout the entire range of a species. They contended that the proposed critical habitat revision for Southern Resident killer whales is overly expansive because it includes most of the geographic area occupied by the species.

Two commenters felt that critical habitat for Southern Resident killer whales should only include those areas within the species' range that are occupied on a regularly occurring or consistent basis. They contested the western and southern boundaries on the basis that areas more than 150 m deep and south of Cape Falcon are not used frequently enough by the Southern Resident killer whales to justify the designation.

Commenters expressed concerns that critical habitat designation would result in fisheries closures year-round to protect areas occupied by the Southern Resident killer whales only at certain times. They requested that the designation be temporally limited to specific periods when Southern Resident killer whales are present in the area, and that adverse modification only be considered for activities that affect the whales during the time that they occupy the areas.

One commenter sought to limit the boundaries of the specific areas based on the spatial extent of each area's primary essential feature. The commenter maintained that because we identified a primary essential feature in each specific area, the designation of critical habitat should be limited to only those spaces within each specific area where the primary essential feature is found.

Response: This critical habitat designation is consistent with our obligations under the ESA. We are not designating the entire geographical area that can be occupied by this species, nor are we designating all areas in which Southern Resident killer whales occur. In regards to designation of unoccupied habitat areas, we considered the best available information, and we are not aware of any unoccupied areas that meet conservation needs of Southern Residents or are essential for conservation (see also response to Comment 2 regarding depth and response to Comment 5 regarding Hood Canal for additional information on areas that commenters requested including). Therefore, we have not included any unoccupied areas in the critical habitat designation. Some Alaskan waters are considered to be within the geographic area occupied by Southern Resident killer whales (see ''Distribution'' section in the Final Biological Report, NMFS 2021a), but we are not designating any areas in Alaska because there is only one sighting in this region and there is insufficient information about the whales' distribution, behavior, and habitat use in these areas. Also, there are limited sightings of Southern Resident killer whales at shallow depths, outside of the eastern, nearshore critical habitat boundaries or beyond the 200-m shelf isobath, outside of the western, offshore critical habitat boundaries (see Specific Areas within the Geographical Area Occupied by the Species and in NMFS 2021a), so the species is able to occupy some areas closer to or farther from shore than we are designating. Finally, Southern Resident killer whales can and do occupy Canadian waters. However, those areas are not included in the designation because they are outside of U.S. jurisdiction. Therefore, this revised critical habitat does not include all areas that can be occupied by Southern Resident killer whales.

Joint NMFS–U.S. Fish and Wildlife Service (USFWS) implementing regulations clarify that the geographical area occupied by the species may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals; 50 CFR 424.02). They also provide that we determine specific areas that contain the physical or biological features essential to the conservation of the species within the geographical area occupied by the species (50 CFR 424.12(b)(1)(iii)). In accordance with these regulations, the areas we are designating as critical habitat, including the waters beyond 150 m in depth and at the southern end of the range in California, are both occupied and contain physical or biological features that are essential to the conservation of the species.

In our satellite tracking data, 7 percent of occurrences were beyond 150 m in depth (NMFS unpublished data, see the Biological Report, NMFS 2021a). These data indicate short duration but regular use of the area by the whales. We acknowledge that satellite-tagged whales swam within a narrower north-south corridor off the coast of California compared to the broader corridor when they were off the coasts of Washington or Oregon (Final Biological Report, NMFS 2021a, section VI.E.). However, using the 200 m depth contour consistently along the West Coast reflects the majority of the whale habitat use data and likely reflects the bathymetric conditions important to conservation including supporting life functions, such as foraging. In addition, establishing different contour lines as boundaries for different specific areas would make implementation unnecessarily complex. As in the proposed rule, we delineate the western boundary of critical habitat in coastal waters at the 200 m depth contour.

With regards to the southern extent of critical habitat in California, we provided scientific data on Southern Resident sightings in this region in the Draft Biological Report (NMFS 2019a, section IV.A.). The sightings in Area 6 (southernmost coastal critical habitat area) around Monterey Bay have been periodic across multiple years (nearly annual from 2007–2011), indicating consistent use of the area from year to year (Hanson *et al.* 2017, Draft and Final Biological Reports, section VI.F.). Furthermore, given the effort it takes for the Southern Resident killer whales to get to this extreme end of their range, recurring use of the area suggests it has special value to the whales and that accessing the area is important to meet their needs. Therefore, the final rule is consistent with the proposed rule and delineates the southern boundary of critical habitat in coastal waters at Point Sur (36°18′00″ N).

Designation of critical habitat does not establish a refuge or sanctuary for the species or automatically close areas to specific activities, but rather it guides Federal agencies to consult with NMFS if their actions may affect critical habitat. In the case of commercial fisheries, as we explain in our responses to Comments 15–17 regarding Economic Impacts and in the FEA (IEc 2021), we consider it unlikely that the designation of critical habitat would result in different fishery management measures than would already be implemented for the protection of Southern Resident killer whales, endangered salmon, and other listed species.

Critical habitat is designated by area, based on where features are present in occupied areas (50 CFR 424.12(b)), rather than time, so we cannot assign a season or other temporal boundary to the designation. However, we can consider the timing of the whales presence in an action area in our section 7 consultations. In these consultations, our analysis of a Federal action's effects on critical habitat will consider the timing of a Federal action and its overlap with time periods in which Southern Resident killer whales are likely to be in the area in order to determine how conservation value of the habitat would be impacted by the Federal action.

In accordance with ESA section 3(5)(A), we delineated specific areas within the geographical area occupied by the species where the essential physical or biological features (PBFs) are found. Although we identify a primary essential feature in each specific area, all three PBFs are essential and present in all specific areas. Potential effects to all three habitat features are subject to evaluation through section 7 consultations. As such, we are not reconsidering the boundaries of specific areas based only on the primary PBFs.

Comment 4: One commenter noted that the proposed critical habitat includes areas of Juan de Fuca Canyon that are deeper than the 200 m depth contour, and felt that these areas should be excluded from the designation because they are outside of the depth band used to define critical habitat.

Response: As detailed in the Draft and Final Biological Reports (NMFS 2019a, 2021a), the 656.2-ft (200-m) isobath was chosen as the western (offshore) boundary of the proposed critical habitat. The narrow Juan de Fuca canyon runs roughly southeast to northwest, bisecting the newly designated critical habitat. Here, the western boundary of the critical habitat aligns with the 200-m isobath to the north and south of the canyon, crossing the deeper mouth of the canyon. The canyon's complex bathymetry, with many islands and inlets where the seafloor is shallower than 200 m, makes strict adherence to a 200-m cutoff impractical. More importantly, as noted in the Draft and Final Biological Reports, the Strait of Juan de Fuca (including the deeper waters of the canyon) is a high use area for the Southern Resident killer whales. Portions of the canyon below 200 m in depth are included in the existing critical habitat designation for inland waters, making the new critical habitat consistent with the previous designation. Therefore, the entire area is included in the designated critical habitat.

Comment 5: One commenter requested that we include Hood Canal in the critical habitat designation. The commenter acknowledged that Southern Resident killer whales have not been documented in Hood Canal since 1995, but argued that the canal could be considered either previously occupied habitat essential to recovery of the species or occupied habitat on the basis that whales alive at the time of listing had been documented in the canal. The commenter also contended that the currently occupied habitat is inadequate for conservation, making it necessary to protect and restore areas that were previously occupied but are now unoccupied areas (even those unoccupied at the time of listing). Also, the commenter felt that efforts to improve salmon abundance in the canal would improve the quality of the habitat and result in conservation benefits when or if Southern Resident killer whales re-enter the canal.

Response: Similar comments were submitted in response to the 2006 proposed rule to designate critical habitat for inland waters (71 FR 34571; June 15, 2006). As described in the 2006 final rule's response to comments (71 FR 69054; November 29, 2006), at that time we considered the best available data and concluded that we lacked sufficient information to either consider Hood Canal as occupied at the time of listing, or to determine that additional unoccupied habitat in Hood Canal was essential for the conservation of the species. With respect to the proposed revision to the critical habitat, the commenter did not provide new information beyond what was previously available, and we have found no additional evidence to consider Hood Canal as either occupied at the time of listing or essential for the conservation of the species.

Section 3(5)(A) of the ESA defines critical habitat as areas either occupied or not occupied by the species at the time that it is listed. For this revision to critical habitat we considered the best available information on killer whale distribution and, similar to our conclusion in 2006, we do not have sufficient data to consider Hood Canal as occupied by the species at the time of listing, nor are there available data supporting that this area is currently occupied by the species. In regards to designation of unoccupied habitat areas, we considered the best available information, and we are not aware of any unoccupied areas, including Hood Canal, that meet conservation needs of Southern Residents or are essential for their conservation. Therefore, we are not designating Hood Canal as either occupied or unoccupied critical habitat. If the whales do return to Hood Canal in response to increasing populations of prey species, we will continue to work with the local community to gather information and reevaluate the importance of Hood Canal as Southern Resident killer whale habitat.

Comment 6: Two commenters opposed the designation of Southern Resident killer whale critical habitat in Southeast Alaska. Another commenter urged NMFS to continue gathering information about the Southern Resident killer whale's use of Alaskan waters to inform potential expansion of critical habitat in the future.

Response: We did not propose and are not designating areas in Southeast Alaskan waters because of the limited information about the whales' distribution, behavior, and habitat use in these areas. NMFS continues to evaluate any reported sightings of killer whales in Alaska for matches to the Southern Resident killer whale DPS.

Unoccupied Areas

Comment 7: One commenter requested that we consider further expanding the area designated as critical habitat to account for potential impacts from climate change. The commenter felt that we had not analyzed the best available science on potential climate change impacts before concluding that insufficient evidence exists to designate unoccupied areas as critical habitat.

Response: Contrary to the commenter's claims, we thoroughly considered all available evidence regarding the potential impacts of climate change on Southern Resident killer whales and presented these findings in the Draft Biological Report (NMFS 2019a). Our guidance provides that ''when designating critical habitat, NMFS will consider proactive designation of unoccupied habitat when there is adequate data to support a reasonable inference that the habitat is essential for the conservation of the species because of the function(s) it is likely to serve as climate changes'' (NMFS 2016). At this time, there exists very little information regarding the potential impacts of climate change on the distribution and habitat use of Southern Resident killer whales over the longer-term, including whether or how the geographic areas occupied by the species might change. The commenter did not cite any additional research or information that would improve our understanding of unoccupied areas that would likely become essential for the conservation of the Southern Resident killer whales as climate changes. Thus, there remains insufficient evidence to identify unoccupied areas based on potential impacts from climate change. As noted in the Biological Report, it will be important to continue monitoring Southern Resident killer whales and their prey to evaluate responses to climate change and ensure appropriate habitat protections.

We also note that we have the authority to revise critical habitat designations as appropriate and in light of new information, which provides a mechanism for addressing and incorporating changing understandings

of the species' use of new areas over time (16 U.S.C. 1533(a)(3)(A)(ii)).

Essential Features

Comment 8: A number of commenters, including those from the Marine Mammal Commission and the state of Washington, requested that we include sound as a fourth essential feature. These commenters pointed out that killer whales rely on sound to navigate, forage, mate, avoid predators, and communicate with one another, and emphasized the impacts of anthropogenic noise on the whales. Several commenters argued that there now exists sufficient information to support including sound as an essential feature, and suggested we consider new science that has emerged since the 2006 designation, and were concerned that considering sound via the prey and passage essential features does not sufficiently address communication space for social behavior, which they pointed out is fundamental to mother-offspring bonding, pod cohesion, and ultimately the health and recovery potential of the DPS. One commenter maintained that by excluding sound as an essential feature, we fail to determine whether sound may require special management considerations or protections. Others were concerned that military activities, specifically would not be adequately addressed. Several commenters emphasized that if sound is not included as an essential feature, then the rule should describe more explicitly how communication space is encompassed within the prey and passage essential features.

Some commenters felt that we did not adequately justify the apparent inconsistency between the approach for Southern Resident killer whales and the approach we took in the critical habitat designations for two other ESA-listed *odontocetes* in U.S. waters: The Cook Inlet beluga whale DPS and the Main Hawaiian Islands insular false killer whale DPS, which include sound as a feature or a characteristic of a feature. Several of these commenters also mentioned Canada's inclusion of sound as an element of critical habitat for Southern Resident killer whales in Canadian waters. They felt the approaches were contradictory, and asked for clarification to reconcile the differences.

One commenter stated their support for our determination in the proposed rule not to include sound as a fourth essential feature, noting the lack of data to support quantitative thresholds. The commenter felt that the effects of sound on the whales are more appropriately considered through the existing procedures for section 7 consultations and Marine Mammal Protection Act (MMPA) incidental take authorizations.

Response: As stated in the proposed rule, we considered the new information on killer whale responses to anthropogenic noise and the acoustic quality of habitats for whale populations that has become available since publication of the 2006 critical habitat designation for Southern Resident killer whales. Much of this new research was presented in the Draft Biological Report supporting the critical habitat proposal and we have incorporated additional publications submitted through the comment period or that have become available in the last year in the Final Biological Report (NMFS 2021a) supporting the final rule. Contrary to the concerns of some commenters, we did not ignore the new research, which enhances our ability to consider the effects of sound on the whales' habitat through the prey and passage essential features, as well as impacts of sound in our analyses of effects to individual whales through section 7 consultations. After carefully considering the studies cited by commenters seeking to include sound as a fourth essential feature, we are still not able to identify specific quantitative in-water sound levels or thresholds for communication, behavioral or displacement impacts on Southern Resident killer whales (as requested by CBD) and we consider effects of sound qualitatively (see further explanation in this comment response, in the section 'Physical and Biological Features Essential to Conservation', and in the Biological Report, NMFS 2021a, section V.B.4). Because potential impacts of sound are already addressed through qualitative section 7 analyses of the prey and passage features, as well as analyses of effects of sound on individual whales themselves, we have not included sound as a separate feature. We will, however, consider results of ongoing and future studies and will review and reconsider this conclusion as our scientific understanding of the acoustic ecology of Southern Resident killer whales advances.

We agree with commenters that communication space for social behavior is important for killer whales, and in the existing inland waters critical habitat, and as expected for the coastal areas designated in this final rule, we will continue to consider the effects of sound on these aspects of the Southern Resident killer whales' life history through the passage and prey essential features as well as in section 7 analyses considering the impacts of noise on the whales themselves. In response to the concerns expressed in the comments, however, we have added more detail to the Final Biological Report (NMFS 2021a, sections V.B.2., V.B.3, and V.B.4) to clarify that the effects of anthropogenic noise on communication and social behavior are and will continue to be evaluated through the prey and passage essential features, as well as analyses of effects to individual whales. Specifically, indirect impacts of anthropogenic noise on communication and social behavior are addressed in section 7 consultations when we consider and address impacts of anthropogenic noise on the whales themselves, which would also take into consideration elements including communication and social behavior as they can relate to the health and fitness of individual whales. Specifically, effects of anthropogenic noise that result in ''take'' (including harm) to individual whales are currently addressed under section 7 of the ESA (pursuant to the standard for considering whether a proposed action would jeopardize the continued existence of the species). For example, the effects of military noise on Southern Resident killer whales and other marine mammals, including on their communication space, are addressed through ongoing NMFS permitting of U.S. Navy Northwest Training and Testing activities (85 FR 33914; June 2, 2020). In addition, if data indicate that anthropogenic noise from a particular Federal action is preventing or impeding access to prey or preventing or impeding successful feeding within designated critical habitat, then such effects could constitute an adverse effect on the prey essential feature and thus the designated critical habitat itself and for that reason would likely also be addressed under section 7 of the ESA (pursuant to the standard for considering whether an action poses destruction or adverse modification to critical habitat). Thus, the critical habitat and essential features as defined in this rule will provide a measure of protection from noise degradation to the extent that an action might cause such noise that would interfere with the whales' ability to use (*e.g.,* move through for foraging, migrating, social behavior, or access prey) and successfully feed (including social communication for prey sharing) within the critical habitat. Furthermore, the critical habitat designations as finalized in this rule will result in the added requirement that Federal agencies explicitly analyze any relevant impacts of noise on Southern Resident prey species.

There are several reasons why the approach to sound for Southern Resident killer whales is compatible with the approaches for the other two species, Cook Inlet beluga whale DPS and the Main Hawaiian Islands insular false killer whale (MHI IFKW) DPS, which include sound qualitatively as a feature or a characteristic of a feature. The MHI IFKW designation considered the effects of sound on navigation, communication, and foraging by including sound as a characteristic of the habitat feature. Similarly, we are able to analyze the equivalent effects for Southern Resident killer whales through the passage and prey features as these similarly address navigation for access to areas, communication for prey sharing, and movement for foraging (access to prey). For Cook Inlet beluga whale critical habitat, the sound feature focuses on identifying noise levels that do not lead to abandonment of the area, providing a level of protection that is equivalent to our consideration of acoustic barriers in the passage feature for Southern Resident killer whales (passage feature addresses access to areas). Therefore, descriptions of both sound essential features for false killer whales and beluga whales inform the qualitative assessment of habitat-related impacts from anthropogenic sound, specifically on passage, access to critical habitat, and use of critical habitat, similar to passage and prey features for Southern Residents killer whales that equally address access and use of critical habitat. Likewise, the critical habitat (Habitat of Special Importance) established by Canada in Canadian waters includes an acoustic environment feature that addresses the effects of anthropogenic underwater noise on life history functions, but all the life history functions that the feature includes are captured in the prey and passage features of critical habitat in U.S. waters, making the two approaches consistent in the level of protection they provide for the species. Finally, no qualitative sound-related feature has been identified for other whale species with larger ranges (like Southern Resident killer whales) such as humpback whales (84 FR 54354; October 9, 2019), North Atlantic right whales (81 FR 4838, January 27, 2016), and north Pacific right whales (68 FR 19000, April 8, 2008).

Consistent with the proposed rule, this final rule does not include sound as an essential feature for Southern Resident killer whale critical habitat. We will continue to consider the habitat-related effects of anthropogenic sound on the whales via the prey and passage essential features, as detailed above.

Comment 9: Many commenters discussed the importance of prey availability for the recovery of Southern Resident killer whales, noting the value of the coastal critical habitat for supporting the whales' access to prey. One commenter felt that our description of the prey feature should provide greater specificity by specifying prey species and priority Chinook salmon runs that constitute essential features, and identifying quantitative thresholds for prey quantity, quality, and availability.

Response: We agree with the commenters' view that prey availability is important to Southern Resident recovery, and we will continue to carry out section 7 consultations to evaluate potential jeopardy to killer whales from fisheries and other activities with a Federal nexus that may impact the whales' prey species. In addition, certain priority Chinook salmon runs consumed by Southern Resident killer whales are also ESA-listed, and we will continue to carry out section 7 consultations on Federal activities that may jeopardize ESA-listed salmon. As stated in the proposed rule and supported by the subsequent Final Draft Risk Assessment for Salmon FMP Impacts to Southern Resident Killer Whales (PFMC 2020) and our recent Biological Opinions on Implementation of the PFMC Salmon FMP (NMFS 2020, NMFS 2021c), we continue to find that there is not sufficient information to establish a specific threshold level of prey abundance and accessibility for ensuring recovery of the whales. While we have used thresholds of low Chinook salmon abundance to describe high risk conditions for the whales, we have not been able to identify a quantitative threshold for a critical habitat prey feature. Even without such a threshold for critical habitat, however, the final rule and Final Biological Report highlight the rigorous scientific information available that supports our evaluation of prey availability as a feature. That supporting information also includes our current understanding of the different prey species important to the whales.

There is extensive evidence that Southern Resident killer whales have a preference for Chinook salmon prey in inland waters in the summer and fall, as well as other species of salmonids at particular times and locations (Final Biological Report, NMFS 2021a). There is emerging scientific information supporting a similar preference for Chinook salmon in coastal waters as longer term studies have documented for inland waters, though the studies in coastal waters have also documented a wider range of prey species in the diet compared to the diet in inland waters. The coastal data, however, are limited (small sample size from limited areas and seasons compared to data for inland waters) and still emerging as research continues. Therefore, we have not specified prey species in the description of the prey feature at this time. However, we will continue to use the best available information on prey species in the diet of the whales and incorporate new information on prey as our understanding evolves, as we have in consultations on the inland waters critical habitat.

Comment 10: One commenter disputed the proposed rule's analysis regarding the relationship between Chinook salmon abundance on the outer coast and the availability of prey for Southern Resident killer whales. The commenter felt that NMFS did not use the best available data in concluding that Chinook salmon abundance on the outer coast may pose a risk to the killer whales, citing several studies for additional consideration. The commenter emphasized the uncertainties that still exist in our understanding of the relationship between Southern Resident killer whales population dynamics and Chinook salmon. They noted the new information available in the Risk Assessment produced by the PFMC's Southern Resident Killer Whale Working Group, and requested that these findings be incorporated into the final rule.

Response: The Draft Biological Report (NMFS 2019a) provided a comprehensive review of the scientific literature on prey availability as a potential threat to Southern Resident killer whales. The Draft Biological Report included studies noted by the commenter for consideration, and acknowledged the limitations and uncertainties of the currently available information. Since the publication of the proposed rule on August 27, 2019, new research has been published in the Final Draft Risk Assessment for Salmon FMP Impacts to Southern Resident Killer Whales (PFMC 2020) and our recent Biological Opinions on Implementation of the PFMC Salmon FMP (NMFS 2020, NMFS 2021c). The Final Biological Report (NMFS 2021a) and FEA (IEc 2021) have been updated to include these new analyses.

Special Management Considerations

Comment 11: Several commenters mentioned the importance of addressing upstream threats to Southern Resident

killer whales' prey, such as sea lion predation, dams, land-based water pollution, and liquefied natural gas terminals. Some of these commenters felt the proposed rule did not go far enough to address these threats, while others felt NMFS should focus on addressing these threats instead of designating critical habitat. Alternative solutions proposed by commenters included increased hatchery production; salmon habitat management, protection, and restoration; dam removal; and sea lion predation management. Commenters emphasized the need to consider activities outside the critical habitat with downstream impacts that could adversely impact essential features of the critical habitat. One commenter requested that NMFS produce a map of areas outside the critical habitat where activities could trigger section 7 consultation.

Response: NMFS leads and supports a wide range of activities that aim to recover Southern Resident killer whales and their prey, including efforts to address upstream threats highlighted by commenters. As one of many tools to support recovery efforts, designating critical habitat provides additional conservation protections for the whales and their habitat. ESA section 7 requires that Federal agencies ensure their actions are not likely to destroy or adversely modify critical habitat. This requirement applies to actions occurring both within and outside of designated critical habitat areas which can impact the features of the critical habitat. For example, consultation would be required on activities that occur in upstream freshwater locations if those actions may affect essential habitat features in designated critical habitat. However, as described in the DEA and FEA (section 1.3, IEc 2019, 2021), no distance threshold can be predetermined for how far upstream from the critical habitat consultation may occur. Therefore, it is not possible to produce a map of areas where certain activities would trigger section 7 consultation.

Comment 12: Several commenters expressed concern about the impacts of vessel traffic on Southern Resident killer whales. One commenter requested that we consider including additional management measures for vessel traffic in the critical habitat final rule, and another requested that we not exclude the San Francisco Bay shipping lanes.

Additionally, several commenters expressed concern about potential changes to vessel traffic management in response to the designation of critical habitat. They were concerned that the critical habitat designation could result in modifications to routing, voyage planning, and navigation restrictions that would adversely impact maritime shipping and towing industries.

Response: The proposed rule identified vessel traffic as one of twelve types of human activities that have the potential to affect the habitat features essential to the conservation of Southern Resident killer whales. The Final Biological Report describes the potential impacts of vessel traffic on, and existing regulations and procedures in place to protect, the whales and their habitat. Vessel traffic has a Federal nexus through the shipping lanes established by the U.S. Coast Guard (USCG) under the Ports and Waterways Safety Act, and the USCG consults with NMFS to evaluate impacts on whales and their critical habitat for the regulatory codification of Traffic Separation Schemes (TSS).

We did not propose to exclude and are not excluding the San Francisco Bay shipping lanes from critical habitat designation, nor do we anticipate that designation will result in changes to the San Francisco Bay TSS. As described in section 2.9 of the DEA and FEA (IEc 2019, 2021), based on our experience with section 7 and informal consultations with USCG regarding codification of TSS, NMFS does not anticipate the expanded critical habitat will generate additional conservation efforts for killer whales associated with vessel traffic management beyond the existing need to avoid jeopardy to the whales.

Comment 13: Two commenters stated that scientific research should be included in the economic analysis as an activity that may be affected by the critical habitat designation. One commenter stated that it was unclear if scientific research activities were considered in the economic analysis, and mentioned that basic marine research supported by the National Science Foundation (NSF) occurs within the proposed critical habitat (*e.g.,* NSF Ocean Observatories Initiative). One commenter recommended that we list this category of activity as part of our summary of activities that may adversely modify the critical habitat or be affected by the designation as required by section 4(b)(8) of the ESA.

Response: The effects of certain scientific research activities on Southern Resident killer whale critical habitat and potential for changes in management of those activities following critical habitat expansion were considered within the discussion of other related activities in the DEA and are still considered in the FEA (IEc 2019, 2021) These activities are directly related to other categories of activities that may affect critical habitat and are, therefore, grouped within those activities instead of as a separate category of activity. For example, seismic-based research is discussed in section 2.12 Geologic Surveys (Including Seismic Surveys), and research related to renewable energy development is discussed in section 2.6. Alternative Energy Development. Fisheries-related scientific research is included under the category of Fisheries in section 2.3. Other types of scientific research were not identified as posing a specific threat to the essential features of Southern Resident killer whale critical habitat, but future consultations on these activities will need to include an analysis of potential effects on critical habitat. In all cases, NMFS has not identified any conservation efforts that will change management of any scientific research activity following the critical habitat expansion. The DEA and FEA do consider the administrative costs to NMFS, the action agency, and third parties relative to this activity associated with future section 7 consultations. These costs are reported in Exhibit 3–9 in the categories of ''Fisheries'' (for fisheries-related research), ''Renewable Energy Development'' (for wind and wave energy research), ''Seismic Surveying'' (for seismic research), and ''Other'' (for other types of research).

Application of ESA Section 4(b)(2)

Economic Impacts

Comment 14: A representative from the USACE Sacramento District commented that consultations in the Sacramento District will need to consider the effects of their permitted activities on Southern Resident killer whale critical habitat, and thus those activities may be affected by the critical habitat expansion. Additionally, costs associated with future section 7 consultations will be incurred by the District.

Response: We thank the commenter for pointing out the oversight in the DEA's exclusion of the Sacramento District from the list of USACE Districts that manage and conduct activities potentially affected by the expansion of critical habitat for Southern Resident killer whales. We agree that because the range of the prey species, which is an essential feature of Southern Resident killer whale critical habitat, extends into the Sacramento District's area of authority, activities in that district may be affected. Consistent with the

comment, we agree that those costs identified in the report as potentially resulting from the critical habitat expansion relative to USACE projects may include projects in the Sacramento District. Because NMFS does not anticipate any changes to the management of USACE permitted or implemented activities, these costs are limited to the administrative costs to NMFS, the USACE, and third party permit applicants of participating in future section 7 consultations. Section 2.10 of the FEA (IEc 2021) includes the Sacramento District in the list of USACE districts that manage activities that may be affected by the expansion (may have administrative costs associated with potential future consultations).

Comment 15: Multiple commenters stated that the economic analysis did not adequately consider the potential costs of the proposed critical habitat designation on fisheries. One commenter noted that nearly all costs identified in the economic analysis are internal costs to NMFS instead of third-party costs to the fishing industry. Commenters acknowledged that NMFS considers additional conservation efforts as a result of critical habitat designation to be unlikely but noted that if this assumption proves false, there could be significant economic impacts to fisheries. The commenters suggested that the economic analysis should provide a full range of potential economic impacts to fisheries, including an analysis of potential fisheries closures. The commenters suggested that such analysis would better inform the fishing industry, as well as better allow NMFS to weigh potential costs versus benefits of the designation.

Response: The DEA considered the potential for the expansion of critical habitat to result in additional conservation efforts, including fishery closures, for commercial and recreational fisheries (see section 2.3). At the time of DEA development, NMFS was not able to envision a scenario in which the expansion of critical habitat for Southern Resident killer whales would result in changes to management of salmon fisheries or fisheries with incidental catch of salmon. This conclusion was due to a number of factors including the ESA listing and consequent need for recovery of many salmon populations themselves, existing consideration of fishery impacts and prey availability relative to the potential for jeopardy to Southern Resident killer whales even absent critical habitat expansion, and experience over the past 15 years implementing the inland waters critical habitat for Southern Resident killer whales, which has not resulted in fishery management changes beyond those considered during ESA consultation on prey effects relative to jeopardy. Since that time, there has been substantial attention to Southern Resident killer whale conservation and recognition of the link between their recovery and salmon abundance, suggesting that numerous factors outside of the potential critical habitat expansion will continue to drive policy decisions related to management of salmon fisheries. As a result, NMFS is unable to envision a scenario in which the expanded designation of critical habitat will result in changes to fishery management. Given this, we have not quantified costs associated with hypothetical management actions that are not anticipated outcomes of this critical habitat rule. Quantified costs are thus limited to those administrative costs incurred as a result of section 7 consultation on fishery management plans.

The administrative costs quantified in the DEA and FEA are not exclusive to NMFS. As shown in Exhibit 1–3 of the FEA, the analysis estimates administrative costs for each forecasted consultation to NMFS, a Federal action agency, and a third party (IEc 2021). A third party to consultation could be a private company (*e.g.,* an applicant for a Federal permit), a local or state government, or some other entity. In the case of fisheries, administrative costs are incurred through the process of consultation on fishery management plans. Although private third parties such as individual fishermen are not generally involved in this process, administrative effort on the part of one or more third parties associated with participation in that process is included in the estimated costs of consultation.

Comment 16: Numerous commenters stressed the need for the economic analysis to consider the value of and potential impacts to fisheries and associated communities in California, Oregon, and Washington. These commenters stated that the critical habitat designation could harm the livelihoods of fishermen and coastal communities all along the West Coast.

Response: The FEA (IEc 2021) recognizes the economic value of fisheries to communities in Washington, Oregon, and California (IEc 2021, section 2.3.1). However, the critical habitat designation is unlikely to result in additional conservation efforts due to baseline protections associated with the ESA-listing status of both the killer whales and salmon, *i.e.,* due to the need to consider the potential for fisheries to jeopardize the species even without a critical habitat designation. As a result, we conclude that the rule will not have economic impacts on fishing activity beyond administrative costs associated with section 7 consultation on fishery management plans.

Comment 17: One commenter expressed the opinion that the economic analysis does not account for certain types of economic costs of the designation to the fishing industry, including delays associated with consultation and litigation. The commenter describes that additional consultations and/or litigation associated with the final rule will result in costs to NMFS that have not been accounted for such as staff resources that are required to administer consultations and/or litigation associated with the final rule. Consultation requirements and litigation could result in costs to the industry, particularly if it results in other important actions being delayed because of this rule.

Response: The administrative time and resources associated with NMFS' participation in consultations resulting from the critical habitat expansion, as well as participation of other Federal agencies and third parties to consultations, are explicitly included in the administrative costs quantified in the FEA (IEc 2021). It would be speculative to estimate costs associated with delays in management actions due to consultation requirements absent data that specifies the nature, extent, and duration of these types of delays, particularly in light of the fact that NMFS does not anticipate that the outcome of consultations would change as a result of the critical habitat expansion.

While potential exists for third party lawsuits to result from critical habitat designation, the likelihood, timing, and outcome of such lawsuits are uncertain. While critical habitat designation may stimulate additional legal actions, data do not exist to reliably estimate impacts. That is, estimating the number, scope, and timing of potential legal challenges would require significant speculation. Furthermore, litigation risk exists regardless of the critical habitat designation given the existing protections already afforded the whales under the MMPA and ESA.

National Security Impacts

Comment 18: Multiple commenters, including the Washington Department of Fish and Wildlife, expressed opposition to the proposed exclusions of the QRS off the coast of Washington and the associated 10-km buffer around this area. Several commenters stated that the proposed exclusion was overly

broad and not adequately justified. Several commenters stated that planned activities, such as use of sonar and explosives, can impact the whales and their prey, and additional mitigation measures or restrictions on the Department of the Navy's (''Navy'') activities within the QRS should be implemented. One commenter noted that the QRS overlaps with the OCNMS, an area that requires a higher standard of resource protection. Several commenters noted that the QRS area was within a high use foraging and passage area for Southern Resident killer whales. Some commenters noted that the 10-km buffer overlaps and is adjacent to priority Chinook salmon rivers and expressed concern that the exclusion may impact their ability to access prey. Several commenters suggested not excluding from the critical habitat designation a north-south nearshore corridor for passage through the QRS. Commenters requested we reconsider the Navy's request for this exclusion given the importance of the area for Southern Resident killer whales.

Acknowledging the requirement to balance military readiness needs when designating critical habitat, one commenter made several points in favor of the exclusion, noting the low number of training and testing events that the Navy expected to carry out within the QRS and that those activities would be subject to review under section 101(a)(5)(A) of the MMPA and section 7 of the ESA.

Response: As discussed in the Draft and Final ESA Section 4(b)(2) Report (NMFS 2019b, 2021b), to weigh the national security impacts against conservation benefits of a potential critical habitat designation, we considered the size of the requested exclusion and the amount of overlap with the specific critical habitat area; the relative conservation value of the particular area for the Southern Resident killer whales; the importance of the site to the Navy mission and military readiness; the likelihood that the Navy's activities would destroy or adversely modify critical habitat, and the likelihood that NMFS would require project modifications to reduce or avoid these impacts; and, the likelihood that other Federal actions may occur in the site that would no longer be subject to the critical habitat provision if the particular area were excluded from the designation. In response to the public comments, we reconsidered these factors, information provided by the Navy, and also requested additional information from the Navy regarding their activities in the portion of the QRS that also falls within the OCNMS.

In making our decision with respect to this particular area, we did so within the framework of our joint NMFS/USFWS policy on implementation of section 4(b)(2) (81 FR 7226, February 11, 2016) (''Section 4(b)(2) Policy''). Specifically, when a DOD agency requests an exclusion on the basis of national-security or homeland security impacts, it must provide a ''reasonably specific justification'' of a probable incremental impact on national security that would result from the designation of that specific area as critical habitat (81 FR 7226; February 11, 2016). Where the request is substantiated with such a reasonably specific justification, we give ''great weight'' to those concerns in analyzing the benefits of exclusion.

The QRS and proposed 10-km buffer comprise about 39 percent of Area 1 (Coastal Washington/Northern Oregon Inshore) and about 25 percent of Area 2 (Coastal Washington/Northern Oregon Offshore), and about 28 percent of Areas 1 and 2 combined, but a very small portion of the total critical habitat designations for the Southern Resident killer whale (8.5 percent). The QRS and associated buffer also have a significant degree of overlap with the OCNMS, where certain activities are prohibited or not authorized, including oil, gas, or mineral exploration, development, or production; discharging or depositing any material or other matter; drilling into, dredging, or otherwise altering the seabed, with some exceptions (15 CFR 922.152). Because of these prohibitions, the likelihood of other Federal activities being proposed in this area of the QRS may be limited.

In support of their request for exclusion of this particular area, the Navy pointed to the extensive range of planned activities, which are described in their Final Northwest Training and Testing (NWTT) Supplemental Environmental Impact Statement (SEIS) published on September 18, 2020, and stated that any additional, future modifications to these activities to minimize impacts on Southern Resident killer whale critical habitat would impact the Navy's ability to meet mission requirements. The Navy pointed to the use of explosives, in particular, as being likely to have adverse effects on killer whale prey, although not likely at the population level for salmon prey. In their initial request, dated December 5, 2018, the Navy stated that if additional mitigation requirements result in having to halt, reduce in scope, or geographically or seasonally constrain testing activities to prevent adverse effects to critical habitat, this would in turn impact its ability to test and field new systems and platforms. To avoid potential, additional, spatial restrictions on its activities within the QRS, the Navy also requested exclusion of an additional 10-km buffer around the QRS from the critical habitat designation. The Navy determined the size for this buffer using sound attenuation modeling to calculate the farthest distance at which fish would be expected to be injured from the largest explosive the Navy can reasonably foresee testing in the QRS; and, in subsequent communications, the Navy further clarified that the size of the buffer also incorporated uncertainty for updates in resource-related science, changes in oceanographic conditions that could reduce attenuation, and the evolution of military technologies that may behave differently in the environment.

We continue to find that the Navy has provided a reasonably specific justification to support the requested exclusion of the QRS, and consistent with our Section 4(b)(2) Policy (81 FR 7226; February 11, 2016), we gave great weight to these concerns when analyzing the benefits of exclusion. Our consideration of the multiple factors discussed, coupled with the potential delay in critical missions in order to complete adverse modification analyses, caused us to continue to find that the benefits of excluding the QRS due to national security impacts outweigh the benefits of designating this portion of Areas 1 and 2 as critical habitat for the Southern Resident killer whales. However, we are modifying our proposed exclusion of the buffer area. Specifically, we are not excluding a portion of the 10 km buffer area around the northeast corner of the QRS, extending along the East side of the QRS, where it overlaps with the OCNMS. As detailed in the Section 4(b)(2) Report (NMFS 2021b), we concluded the benefits of designating critical habitat for Southern Resident killer whales within this portion of the buffer are not outweighed by national security impacts of including that portion at this time.

We acknowledge the concerns raised by the commenters regarding potential impacts to the whales and their prey as a result of certain Navy activities, such as sonar and explosives. The Biological and Conference Opinion on the Navy's Northwest Training and Testing Activities, issued by NMFS on October 19, 2020, addresses activities within the QRS and analyzed the effects of the Navy's planned activities on Southern Resident killer whales as well as their prey. As discussed in that consultation,

the Navy has adopted certain mitigation measures within the QRS, including the portion of the QRS that overlaps with the OCNMS, to avoid or minimize adverse impacts on marine mammals and other marine resources in this area. Exclusion of the QRS area will not impact our ability to continue to work closely with the Navy through the section 7 consultation process to minimize and mitigate impacts to the Southern Resident killer whales as a result of the Navy's testing and training activities (see 85 FR 72312; November 12, 2020, and *https://www.fisheries.noaa.gov/action/incidental-take-authorization-us-navy-northwest-training-and-testing-nwtt-2020*).

Critical Habitat Identification

In the following sections, we describe the relevant definitions and requirements in the ESA and our implementing regulations and the key information and criteria used to prepare this revision to the Southern Resident killer whale critical habitat designation. In accordance with section 4(b)(2) of the ESA and our implementing regulations (50 CFR 424.12), this designation is based on the best scientific information available.

We followed a five-step process in order to identify the specific areas eligible for critical habitat designation: (1) Determine the geographical area occupied by the species at the time of listing, (2) identify physical or biological habitat features essential to the conservation of the species, (3) delineate specific areas within the geographical area occupied by the species on which are found the physical or biological features, (4) determine whether the feature(s) in a specific area may require special management considerations or protection, and (5) determine whether any unoccupied areas are essential for conservation. Our evaluation and determinations are described in detail in the Final and Draft Biological Reports (NMFS 2019a, NMFS 2021a) and are summarized below.

Beyond the identification and description of the areas, the critical habitat designation process also includes additional steps: Identify whether any area may be precluded from designation because the area is subject to an INRMP that we have determined provides a benefit to the species; and consider the economic, national security, or any other relevant impacts of designating critical habitat and determine whether to exercise our discretion to exclude any particular areas. These steps are described in the Final ESA Section 4(b)(2) Report (NMFS 2021b) and the FEA (IEc 2021) and are summarized in later sections of this rule.

Geographical Area Occupied by the Species

The term ''geographical area occupied by the species'' is defined as an area that may generally be delineated around a species' occurrences as determined by the Secretary (*i.e.,* range). Such areas may include those areas used throughout all or part of the species' life cycle, even if not used on a regular basis (*e.g.,* migratory corridors, seasonal habitats, and habitats used periodically, but not solely by vagrant individuals) (50 CFR 424.02).

Southern Resident killer whale summer inland habitat use was previously described in the 2006 critical habitat designation (71 FR 69054, November 29, 2006). At that time, few data were available on Southern Resident distribution and habitat use of coastal and offshore areas in the Pacific Ocean. While it was known that the whales occupied these waters for a portion of the year, only 28 sightings of Southern Resident killer whales were available to describe their coastal range (Krahn *et al.* 2004, NMFS 2006). In the 2006 designation, these coastal areas were included in the identified geographical area occupied by the species, but the lack of data precluded the agency from designating specific areas within the coastal range as critical habitat.

Since the 2006 designation, considerable effort has been made to better understand the range and movements of Southern Resident killer whales once they leave inland waters. Land- and vessel-based opportunistic and survey-based visual sightings, satellite tracking, and passive acoustic research conducted since 2006 have provided an updated estimate of the whales' coastal range that extends from the Monterey Bay area in California, north to Chatham Strait in Southeast Alaska. In addition, these data have provided a better understanding of the whales' use of these waters, allowing us to identify areas that meet the definition of critical habitat under the ESA.

While the range of Southern Resident killer whales includes coastal and inland waters of British Columbia, Canada, we cannot designate critical habitat in areas outside of U.S. jurisdiction (50 CFR 424.12(g)). The Government of Canada has designated critical habitat for Northern and Southern Resident killer whales in Canadian waters under its Species at Risk Act. In its 2008 recovery strategy and 2011 amended recovery strategy, the Government of Canada identified the Canadian side of Haro and Juan de Fuca Straits, as well as Boundary Pass and adjoining areas in the Strait of Georgia as critical habitat for Southern Resident killer whales (Fisheries and Oceans Canada 2011). The Government of Canada recently designated a new critical habitat area for Northern and Southern Resident killer whales in ocean waters on the continental shelf off southwestern Vancouver Island, including Swiftsure and La Pérouse Banks (Fisheries and Oceans Canada 2018).

Some Alaskan waters are considered to be within the geographic area occupied by Southern Resident killer whales, but we are not expanding critical habitat there at this time because there is insufficient information about the whales' distribution, behavior, and habitat use in these areas. For example, there is only one sighting of Southern Resident killer whales in Southeast Alaska, in Chatham Strait in 2007. While we can infer that some of the essential habitat features, such as prey, are present to support the whales there, we do not have sufficient data to adequately describe Southern Resident use of habitat features in this area or identify specific areas with those features.

Physical and Biological Features Essential to Conservation

The ESA does not specifically define physical or biological features. However, court decisions and joint NMFS and USFWS regulations at 50 CFR 424.02 (81 FR 7413; February 11, 2016) provide guidance on how physical or biological features are expressed. Physical and biological features support the life-history needs of the species, including but not limited to, water characteristics, soil type, geological features, sites, prey, vegetation, symbiotic species, or other features. A feature may be a single habitat characteristic, or a more complex combination of habitat characteristics. Features may include habitat characteristics that support ephemeral or dynamic habitat conditions. Features may also be expressed in terms relating to principles of conservation biology, such as patch size, distribution distances, and connectivity.

Based on the best available scientific information regarding natural history and habitat needs, the following features were identified in the 2006 critical habitat designation as essential to the conservation of the species within inland waters of Washington: (1) Water

quality to support growth and development; (2) prey species of sufficient quantity, quality and availability to support individual growth, reproduction and development, as well as overall population growth; and (3) passage conditions to allow for migration, resting, and foraging. We identified the same three biological and physical features as essential for the conservation of Southern Resident killer whales within their coastal range, as described below.

(1) *Water quality to support growth and development.* Water quality supports Southern Resident killer whales' ability to forage, grow, and reproduce free from disease and impairment. Southern Resident killer whales are highly susceptible to biomagnification of pollutants, such that chemical pollution is considered one of the prime impediments to their recovery (NMFS 2008). Water quality is essential to the whales' conservation, given the whales' present contamination levels, small population numbers, increased extinction risk caused by any additional mortalities, and geographic range (and range of their primary prey) that includes highly populated and industrialized areas. Water quality is especially important in high-use areas where foraging behaviors occur and contaminants can enter the food chain. The absence of contaminants or other agents of a type and/or amount that would inhibit reproduction, impair immune function, result in mortalities, or otherwise impede the growth and recovery of the Southern Resident population is a habitat feature essential for the species' recovery. Exposure to oil spills also poses additional direct threats as well as longer-term population level impacts. Therefore, the absence of these chemicals is essential to Southern Resident conservation and survival.

(2) *Prey species of sufficient quantity, quality and availability to support individual growth, reproduction and development, as well as overall population growth.* Southern Resident killer whales need to maintain their energy balance all year long to support daily activities (foraging, traveling, resting, socializing) as well as gestation, lactation, and growth. Maintaining their energy balance and body condition is also important because when stored fat is metabolized, lipophilic contaminants may become more mobilized in the bloodstream, with potentially harmful health effects (Mongillo *et al.* 2016). Southern Resident killer whales are top predators that show a strong preference for salmonids in inland waters, particularly larger, older age class Chinook (age class of 3 years or older) (Ford & Ellis 2006, Hanson *et al.* 2010). Samples collected during observed feeding activities, as well as the timing and locations of killer whales' high-use areas that coincide with Chinook salmon runs, suggest the whales' preference for Chinook salmon extends to outer coastal habitat use as well (Hanson *et al.* 2017, Shelton *et al.* 2018, Hanson *et al.* 2021). At some low Chinook abundance level, the prey available to the whales will not be sufficient to forage successfully leading to adverse effects on body condition or fecundity (NMFS 2020). Habitat conditions should support the successful growth, recruitment, and sustainability of abundant prey to support the individual growth, reproduction, and development of Southern Resident killer whales.

Age, size, and caloric content all affect the quality of prey, as do contaminants and pollution. The availability of key prey is also essential to the whales' conservation. Availability of prey along the coast is likely limited at particular times of year due to the small run sizes of some important Chinook salmon stocks, as well as the distribution of preferred adult Chinook salmon that may be relatively spread out prior to their aggregation when returning to their natal rivers. Availability of Chinook salmon to the whales may also be impacted by sound from vessels or other sound sources if they raise average background noise within the animal's critical bandwidth to a level that is expected to chronically or regularly reduce echolocation space (Joy *et al.,* 2019, Veirs *et al.* 2016), and by competition from other predators including other resident killer whales, pinnipeds, and fisheries (Chasco *et al.* 2017).

(3) *Passage conditions to allow for migration, resting, and foraging.* Southern Resident killer whales are highly mobile, can cover large distances, and range over a variety of habitats, including inland waters and open ocean coastal areas from the Monterey Bay area in California north to Southeast Alaska. The whales' habitat utilization is dynamic. Analyses of Southern Resident killer whales' movement patterns on the outer coast from satellite tag data have revealed preferred depth bands and distances from shore that suggest potential travel corridors, and variations in travel speed or duration of occurrence that may indicate different behavioral states (Hanson *et al.* 2017).

Southern Resident killer whales require open waterways that are free from obstruction (*e.g.,* physical, acoustic) to move within and migrate between important habitat areas throughout their range, find prey, communicate, and fulfill other life history requirements. As an example of an ''acoustic obstruction,'' killer whale occurrence in the Broughton Archipelago, Canada declined significantly when acoustic harassment devices were in use at a salmon farm, and returned to baseline levels once the devices were no longer used (Morton & Symonds 2002), indicating the introduction of this chronic noise source into the environment acted as an acoustic barrier and/or deterrent to the whales' use of the area. The passage feature may be less likely to be impacted in coastal ocean waters compared to the more geographically constricted inland waters because the whales may be able to more easily navigate around potential obstructions in the open ocean, but these passage conditions are still a feature essential to the whales' conservation and which may require special management considerations or protection.

We also considered whether to identify sound as a fourth essential feature. Southern Resident killer whales produce and detect sounds for communication, navigation, and foraging. An acoustic environment, or soundscape, in which the whales can detect and interpret sounds is critical for carrying out these basic life functions. In recognition of this, we previously considered identifying sound as a potential essential feature (69 FR 76673; December 22, 2004), but ultimately concluded that we lacked sufficient information to do so. CBD petitioned us to again consider identifying in-water sound as an essential feature of the currently designated critical habitat and any new designation.

We considered the request and examined new information that has become available since publication of the 2006 critical habitat designation final rule, but similar to limitations in our knowledge in 2006, at this time we are not able to identify specific in-water sound levels or thresholds for communication, behavioral or displacement impacts as specifically requested in the petition by CBD. More importantly, we are able to assess adverse habitat-related effects of anthropogenic sound by evaluating impacts to the prey and passage essential features of current critical habitat for Southern Resident killer whales, as well as to the whales themselves, and thus we do not consider it necessary to identify sound as a separate essential feature. The final rule is consistent with the proposed rule

(84 FR 49214, September 19, 2019) and does not include sound as an essential feature for Southern Resident killer whale critical habitat. We will continue to consider the habitat-related effects of anthropogenic sound on the whales via the prey and passage essential features, as detailed in this section. Under the ESA, we separately consider effects of anthropogenic sound on individual whales (which is scaled up to the listed species unit) and habitat-related impacts (which is scaled up to the critical habitat designation). For the former, NMFS has an established framework and thresholds for considering impacts to marine mammals' hearing (specifically temporary or permanent hearing loss), as outlined in our ''Technical Guidance for Assessing the Effects of Anthropogenic Sound on Marine Mammal Hearing'' (NMFS 2018), and NMFS is also working to refine our guidance on the effects of anthropogenic sound on marine mammal behavior. We will continue to evaluate and manage direct and indirect effects (including consideration of noise interference with whale communication and social behavior) of anthropogenic sound on individual animals and the population relative to the jeopardy standard in ESA section 7 analyses and through MMPA incidental take authorizations.

Adverse habitat-related effects may stem from the introduction of a chronic noise source that degrades the value of habitat by interfering with the sound-reliant animal's ability to gain benefits from that habitat (*i.e.,* altering the conservation value of the habitat). NMFS does not currently have a methodology to establish quantifiable thresholds for determining when chronic noise reaches a level such that it alters the conservation value in this way. However, we can, and do, consider these effects qualitatively.

In our experience evaluating effects to Southern Resident killer whale critical habitat in inland waters, we are able to assess adverse habitat-related effects of anthropogenic sound by evaluating impacts to the prey and passage essential features of current critical habitat for Southern Resident killer whales, and thus we do not consider it necessary to identify sound as a separate essential feature. For example, we evaluate whether chronic anthropogenic sound might alter the conservation value of habitat by reducing the availability of the whales' prey in a particular foraging area by reducing the effective echolocation space for the whales to forage or communicate, or creating a barrier that restricts movements through or within an area necessary for migration, resting, social behavior, or foraging. Thus, the prey and passage essential features as defined in this rule will provide a measure of protection from noise degradation to the extent that an action might cause such noise that would interfere with the whales' ability to use (*e.g.,* move through as in passage or access prey) and successfully feed within the critical habitat (prey feature, including social communication for prey sharing). We will use the same approach for evaluating these effects in coastal critical habitat, consistent with our existing practice in inland waters critical habitat.

In response to public comments requesting that the final rule include sound as an essential feature and emphasizing the importance of communication space for social behavior and pod cohesion (see Comment 8 and response), we revised the Biological Report to clarify that the effects of sound on communication and social behavior are considered in the passage and prey features (as well as effects of sound on individual whales themselves via section 7, outside of critical habitat designation, see sections V.B.2–4, Final Biological Report, NMFS 2021a). Additionally, we will continue to consider and address impacts of anthropogenic noise on the whales themselves, which would also take into consideration elements including communication and social behavior as they can relate to the health and fitness of individual whales.

Specific Areas Within the Geographical Area Occupied by the Species

The three specific areas within the geographic area (range) occupied by the species identified in the 2006 critical habitat designation are carried forward unchanged by the critical habitat revision. We refer to them here as Inland Waters Areas 1–3 to differentiate them from the six newly designated specific coastal areas (Coastal Areas 1–6). In the 2006 designation, a lack of data precluded us from determining whether any specific areas within the coastal range met the definition of critical habitat. Research and data collected since then have allowed us to better characterize the whales' habitat use (NMFS 2021a). These data are now sufficient to identify specific areas within the whales' coastal range.

CBD requested that we identify critical habitat in areas of the Pacific Ocean between Cape Flattery, Washington, and Point Reyes, California, extending approximately 47 mi (76 km) offshore. This requested area was based mainly on the extent of the whales' movements from NMFS' satellite tag data: Tagged animals traveled as far south as Point Reyes and as far offshore as 47 mi. However, the petition stated that because NMFS was continuing to analyze data describing the Southern Resident killer whales' use of coastal and offshore waters, the petition requested we ''refine this proposal, as necessary, to include additional inhabited zones or to focus specifically on areas of concentrated use'' (CBD 2014). To delineate specific areas, we relied on the satellite tag data but also incorporated information on sightings, acoustic data, and prey sampling. As a result, our specific areas differ in their boundaries from the petitioner's request. For example, there are documented sightings of Southern Resident killer whales south of Point Reyes, so the boundary of the critical habitat is farther south than the petitioners requested.

We identified six specific areas off the U.S. West Coast, delineated based on their habitat features, including variation in the primary feature, and variation in predominant habitat use (for example foraging versus traveling) by Southern Resident killer whales. They encompass most (but not all) of the whales' U.S. coastal range, and vary in size. The ESA and our regulations provide the agency discretion to determine the scale at which specific areas are identified (50 CFR 424.12; 81 FR 7413; February 11, 2016). We selected the boundaries between areas to reflect the spatial scale of the whales' movements and behavioral changes (*e.g.,* where tagged whales were primarily traveling versus observed foraging), as well as to align with some existing fishery management boundaries (*e.g.,* Pigeon Point and Point Sur are geographic points used by the PFMC in salmon management; PFMC 2016). Each area contains all three essential features, but the primary feature varies by area and the primary feature of each area is noted below. Identifying six areas with varying primary features, instead of just one comprehensive critical habitat area containing all three features, will assist with section 7 consultations and analyses about how actions would affect the conservation value of an area based on the primary feature. In addition, identifying six areas rather than one also assisted in analyzing benefits and costs in the ESA Section 4(b)(2) Report (NMFS 2021b). More information about each area, including descriptions of the whales' use of the area based on sighting, satellite tagging, and acoustic detection data, can be found in the Final Biological Report (NMFS 2021a). All

area sizes are based on best available spatial data at the time of the final rule.

Beginning at the westernmost extent of the previously designated Strait of Juan de Fuca critical habitat area (Inland Waters Area 3), the new coastal areas span the U.S. West Coast from the U.S. international border with Canada south to Point Sur, California, which is just south of the southernmost sightings of Southern Resident killer whales in Monterey Bay. On January 27, 2008, Southern Resident killer whales were sighted off Cypress Point, Carmel Bay, just south of Monterey Bay, traveling south (N. Black, Monterey Bay Whale Watch, Orca Network sightings archives). Given uncertainty in the exact extent of the whales' southward movements, we elected to delineate the southern boundary of the specific area just south of the last sighting (by approximately 20 mi (32.2 km)) and align the boundary with the existing salmon management area boundary at Point Sur, California (PFMC 2016).

The inshore (eastern) boundary of the areas is delineated by a continuous line along the coast at 20-ft (6.1–m) depth relative to mean high water. This continuous line crosses river mouths and entrances to semi-enclosed bays and estuaries at the 20 ft depth contour where available or crossing at significant barriers (*e.g.,* jetties). Based on the available data, we defined the shoreward boundary of the specific areas as a line along the coast at 20 ft (6.1 m) in depth relative to the mean high water line. Southern resident killer whales rarely occur in waters shallower than 20 ft (6.1 m). For example, based on data from four satellite-tagged Southern Resident killer whales, less than 1 percent of the whales' outer coastal locations were in depths less than 6 m (approximately 20 ft) (NWFSC unpubl. Data, see the Biological Report, NMFS 2021a) (but locations based on satellite tags are not exact and tidal conditions are unknown for these observations). In addition, there are no data from sightings or satellite tags to indicate that Southern Resident killer whales enter river mouths or semi-enclosed bays and estuaries along the coast, although data indicate the whales do use the open embayment of Monterey Bay in California. Finally, the inward boundary is consistent with the inshore boundary of the 2006 critical habitat designation in inland waters (although the inshore boundary of the coastal critical habitat is delineated relative to the mean high water line instead of extreme high water, the inshore boundary in inland waters) and the proposed rule (84 FR 49214, September 19, 2019).

The offshore (western) boundary of the areas is the 656.2 ft (200 m) depth contour, or isobath. This was selected because movement data from satellite-tagged Southern Resident killer whales indicate that most coastal locations were in water depths of 200 m or less (96.5 percent) and within 21.1 mi (34 km) from shore (95 percent) (Hanson *et al.* 2017). Additionally, the limited information available on the distribution of salmon in offshore waters indicates Southern Resident killer whale prey (an essential feature of the habitat) is present in waters of 200 m or less. The two areas off the coast of Washington share the same northern and southern boundaries but are separated longitudinally at the 50-m isobath, such that Coastal Area 1 ranges from 6.1–50 m depth while Coastal Area 2 ranges from 50–200 m depth. The 50-m isobath was selected to distinguish the areas because the majority (42 of 52, or 76.4 percent) of prey samples from observed Southern Resident killer whale predation events in these two areas were collected in water depths of 50 m or less, and just over half of the satellite tag locations in these two areas (54 percent) were in water depths of 50 m or less (NWFSC unpubl. data; Hanson *et al.* 2021, see the Biological Report, NMFS 2021a).

The latitudinal boundaries between the specific coastal areas were initially selected to coincide with some of the coastal salmon management area boundaries as defined in the Pacific Salmon FMP and used for the management of salmon harvest (Chinook and Coho specifically) (PFMC 2016). Although the areas of highest Southern Resident killer whale occurrence, as indicated by a duration-of-occurrence model from satellite tag data (Hanson *et al.* 2017), did not precisely match the salmon management areas, they generally align with the available information on salmonid and other fish species that may be prey to Southern Resident killer whales. For example, the whales' highest use areas occurred in the North of Falcon fishery management area between Cape Falcon, Oregon and the Canadian border, and relatively high use occurred within the Klamath Management Zone. Similar to inland waters, we assume that Southern Resident killer whales respond to regional and seasonal abundance of salmon, particularly Chinook salmon runs. We then adjusted some of the boundaries to better reflect what we know about the whales' use of the areas (*e.g.,* areas where foraging has been observed and/or prey samples collected, versus areas where whales are considered mainly to be traveling through). We selected Cape Meares, Oregon, as the southern boundary of Areas 1 and 2 instead of Cape Falcon just to the north, because the Cape Meares boundary encompassed all but one of the observed predation events and prey sample locations off the Washington and Oregon coasts. We selected Cape Mendocino, California, as the boundary between Areas 4 and 5 instead of Horse Mountain just to the south because the three predation events observed in California occurred off the Eel River just north of Cape Mendocino, and that boundary better demarcated the southern extent of a higher-use area based on the duration-of-occurrence model of satellite-tagged whale movements (NMFS 2021a).

The six specific coastal areas are:

Coastal Area 1—Coastal Washington/Northern Oregon Inshore Area: U.S. marine waters west of a line connecting Cape Flattery, Washington (48°23′10″ N/124°43′32″ W), Tatoosh Island, Washington (48°23′30″ N/124°44′12″ W), and Bonilla Point, British Columbia (48°35′30″ N/124°43′00″ W), from the U.S. international border with Canada south to Cape Meares (45°29′12″ N), between the 6.1–m and 50–m isobath contours. This area covers 1,437.9 mi^2 (3,724.2 km^2) and includes waters off Clallam, Jefferson, Grays Harbor, and Pacific counties in Washington and Clatsop and Tillamook counties in Oregon. The primary essential feature of this area is prey.

Coastal Area 2—Coastal Washington/Northern Oregon Offshore Area: U.S. marine waters west of a line connecting Cape Flattery, Washington (48°23′10″ N/124°43′32″ W), Tatoosh Island, Washington (48°23′30″ N/124°44′12″ W), and Bonilla Point, British Columbia (48°35′30″ N/124°43′00″ W), from the U.S. international border with Canada south to Cape Meares (45°29′12″ N), between the 50-m and 200-m isobath contours. This area covers 4,617.2 mi^2 (11,958.6 km^2), and as with Area 1, includes waters off Clallam, Jefferson, Grays Harbor, and Pacific counties in Washington and Clatsop and Tillamook counties in Oregon. The primary essential feature of this area is prey.

Coastal Area 3—Central/Southern Oregon Coast Area: U.S. marine waters from Cape Meares (45°29′12″ N) south to the OR/CA border (42°00′00″ N), between the 6.1-m and 200-m isobath contours. This area covers 4,962.6 mi^2 (12,853.1 km^2) and includes waters off Tillamook, Lincoln, Lane, Douglas, Coos, and Curry counties in Oregon. The primary essential feature of this area is passage.

Coastal Area 4—Northern California Coast Area: U.S. marine waters from the OR/CA border (42°00′00″ N) south to Cape Mendocino, CA (40°26′19″ N), between the 6.1–m and 200-m isobath contours. This area covers 1,606.8 mi² (4,161.5 km²) and includes waters off Del Norte and Humboldt counties in California. The primary essential feature of this area is prey.

Coastal Specific Area 5—North Central California Coast Area: U.S. marine waters from Cape Mendocino, CA (40°26′19″ N) south to Pigeon Point, CA (37°11′00″ N), between the 6.1-m and 200-m isobath contours. This area covers 3,976.2 mi² (10,298.4 km²) and includes waters off Humboldt, Mendocino, Sonoma, Marin, San Francisco, and San Mateo counties in California. The primary essential feature of this area is passage.

Coastal Specific Area 6—Monterey Bay Area: U.S. marine waters from Pigeon Point, CA (37°11′00″ N) south to Point Sur, CA (36°18′00″ N), between the 6.1-m and 200-m isobath contours. This area covers 709.7 mi² (1,838.2 km²) and includes waters off San Mateo, Santa Cruz, and Monterey counties in California. The primary essential feature of this area is prey.

Need for Special Management Considerations or Protection

Joint NMFS and USFWS regulations at 50 CFR 424.02 define special management considerations or protection to mean methods or procedures useful in protecting physical and biological features essential to the conservation of listed species.

Human activities managed under a variety of legal mandates have the potential to affect the habitat features essential to the conservation of Southern Resident killer whales, including those that could increase water contamination and/or chemical exposure, decrease the quantity or quality of prey, or could inhibit safe, unrestricted passage between important habitat areas to find prey and fulfill other life history requirements. Examples of these types of activities include (but are not limited to): (1) Salmon fisheries and fisheries that take salmon as bycatch; (2) salmon hatcheries; (3) offshore aquaculture/mariculture; (4) alternative energy development; (5) oil spills and response; (6) military activities; (7) vessel traffic; (8) dredging and dredge material disposal; (9) oil and gas exploration and production; (10) mineral mining (including sand and gravel mining); (11) geologic surveys (including seismic surveys); and (12) activities occurring adjacent to or upstream of critical habitat that may affect essential features, that we refer to as ''upstream'' activities (including activities contributing to point-source water pollution, power plant operations, liquefied natural gas terminals, desalinization plants). We identified these activities based on our ESA section 7 consultation history since 2006 for existing Southern Resident killer whale critical habitat, along with additional information that has become available since the original designation. This is not an exhaustive or complete list of potential activities; rather, these activities are of primary concern because of their potential effects that we are aware of at this time and that should be considered in accordance with section 7 of the ESA when Federal agencies authorize, fund, or carry out these activities. The ESA section 7 requirement that Federal agencies ensure their actions are not likely to destroy or adversely modify critical habitat applies not only to actions occurring within designated critical habitat, but also to actions occurring outside of designated areas which may impact the features of the critical habitat. For example, consultation would be required on activities that occur in waters shallower than 20 ft (6.1 m) or in upstream freshwater locations if those actions are likely to adversely affect essential habitat features in designated critical habitat.

Table 1 lists the activities that may affect the essential features in each of the six specific coastal areas such that the essential features may require special management or consideration. The Final Biological Report (NMFS 2021a) and FEA (IEc 2021) provide a more detailed description of the potential effects of these activities on the essential features.

TABLE 1—SIZE OF EACH SPECIFIC AREA AND ACTIVITIES THAT MAY AFFECT THE ESSENTIAL FEATURES AND NECESSITATE THE NEED FOR SPECIAL MANAGEMENT CONSIDERATIONS OR PROTECTION WITHIN EACH AREA ARE LISTED. SOME ACTIVITIES OCCUR UPSTREAM BUT MAY AFFECT FEATURES IN THE SPECIFIC AREA

Specific area	Size (mi²) *	Activities
1—Coastal Washington/Northern Oregon Inshore Area	1,437.9	FISH, HAT, SPILL, MIL, VESS, DR, POLL, PP.
2 —Coastal Washington/Northern Oregon Offshore Area	4,617.2	FISH, HAT, SPILL, MIL, VESS, DR, POLL, PP.
3—Central/Southern Oregon Coast Area	4,962.6	FISH, HAT, EN, SPILL, MIL, VESS, DR, GEO, POLL, PP, LNG.
4—Northern California Coast Area	1,606.8	FISH, HAT, SPILL, MIL, VESS, DR, POLL, PP.
5—North Central California Coast Area	3,976.2	FISH, HAT, SPILL, MIL, VESS, DR, MIN, POLL, PP.
6—Monterey Bay Area	709.7	FISH, HAT, SPILL, VESS, DR, POLL, PP, DESAL.

Activities: FISH = fisheries, HAT = hatcheries, EN = alternative energy projects, SPILL = oil spills and response, MIL = military activities, VES = vessel traffic, DR = dredging and dredge material disposal, MIN = mineral mining, GEO = geologic surveys, POLL = point-source water pollution, PP = power plants, LNG = LNG terminals, DESAL = desalinization plants.

* Revisions to area size from proposed are based on best available spatial data at the time of the final rule.

Unoccupied Areas

The ESA section 3(5)(A)(ii) definition of critical habitat includes unoccupied areas, which are defined as specific areas outside the geographical area occupied by the species at the time it is listed if such areas are determined to be essential to the conservation of the species. At the present time, we have not identified additional specific areas outside the geographic area occupied by Southern Resident killer whales that may be essential for the conservation of the species. We considered potential future impacts that climate change might have on the geographical area occupied by the whales, particularly with respect to shifts in distribution of their salmon prey. In accordance with NMFS guidance on the treatment of climate change in NMFS ESA decisions (NMFS 2016), we determined that there is insufficient evidence to identify unoccupied areas that are essential to the conservation of Southern resident killer whales based on potential impacts from climate change.

Application of ESA Section 4(a)(3)(B)(i) (Military Lands)

Section 4(a)(3)(B) of the ESA prohibits designating as critical habitat any lands or other geographical areas owned or

controlled by DOD, or designated for its use, that are subject to an INRMP prepared under section 101 of the Sikes Act (16 U.S.C. 670a), if the Secretary of Commerce determines in writing that such a plan provides a benefit to the species for which critical habitat is being designated.

DOD (Army, Navy, and Air Force) helped us identify military lands that may overlap with areas under consideration for critical habitat. The Navy identified two military installations adjacent to these areas, both of which have INRMPs in place for land-based installation activities: Pacific Beach Annex, Naval Station Everett, Washington, and Naval Support Activity (NSA) Monterey, California. Based on our review of these plans, these two shore-based military areas covered by INRMPs do not overlap the critical habitat areas, and thus the critical habitat areas are not subject to the INRMPs or ineligible for designation (see section III.F of the Final ESA Section 4(b)(2) Report, NMFS 2021b).

Application of ESA Section 4(b)(2)

The foregoing discussion describes those areas that are eligible for designation as critical habitat. Specific areas eligible for designation are not automatically designated as critical habitat. As described previously, section 4(b)(2) of the ESA requires that the Secretary consider the economic impact, impact on national security, and any other relevant impacts. The Secretary may exclude an area from designation if he determines the benefits of exclusion outweigh the benefits of designation based on the best available scientific and commercial data. The Secretary may not exclude an area from designation if exclusion of that area will result in the extinction of the species.

The first step in conducting an ESA section 4(b)(2) analysis is to identify the ''particular areas'' to be analyzed. Section 3(5)(A) of the ESA defines critical habitat as ''specific areas,'' while section 4(b)(2) of the ESA requires the agency to consider certain factors before designating any ''particular area.'' The ESA and regulations provide the agency discretion to determine the scale at which specific areas (50 CFR 424.12) and impacts (50 CFR 424.19) are identified. For this revision to the designation of Southern Resident killer whale critical habitat, we identified six ''specific'' areas off the coasts of Washington, Oregon, and California, as described above. For our economic impact analysis, we defined the ''particular areas'' to be equivalent to the ''specific areas.'' This approach and scale allowed us to most effectively consider the conservation value of the different areas when balancing conservation benefit of designation against economic benefits of exclusion. Where we considered impacts on national security or impacts on tribes, we based the ''particular areas'' on land ownership or control (*e.g.,* land controlled by the DOD within which national security impacts may exist, or Indian lands). This approach and scale allowed us to consider impacts and benefits associated with management by the military or land ownership and management by Indian tribes.

Identify and Determine Impacts of Designation

The primary impact of a critical habitat designation stems from the requirement under section 7(a)(2) of the ESA that Federal agencies ensure that their actions are not likely to result in the destruction or adverse modification of critical habitat. Determining this impact is complicated by the fact that section 7(a)(2) contains the associated requirement that Federal agencies must also ensure their actions are not likely to jeopardize the species' (in this case the DPS') continued existence. The true impact of this designation is the extent to which Federal agencies modify their actions to ensure their actions are not likely to destroy or adversely modify the critical habitat of the DPS, beyond any modifications they would make because of the DPS' listing and the jeopardy provision, and the associated increase in consultation costs. Additional, indirect impacts of designation include state and local protections that may be triggered as a result of the designation.

In determining the impacts of designation, consistent with our regulations (50 CFR 424.19) and policy (81 FR 7226; February 11, 2016), we focused on identifying the incremental impacts. To determine the incremental impacts of the revised designation, we examined what the state of the world would be with and without the addition of coastal critical habitat for Southern Resident killer whales. The ''without the coastal critical habitat'' scenario represents the baseline for the analysis. It includes process requirements and habitat protections already afforded Southern Resident killer whales under their Federal listing or under other Federal, state, and local regulations. The ''with coastal critical habitat'' scenario describes the incremental impacts associated specifically with the designation of coastal critical habitat for Southern Resident killer whales. The primary potential impacts of critical habitat designation we identified were: (1) The economic costs associated with additional administrative effort of including a coastal critical habitat analysis in section 7 consultations for Southern Resident killer whales, (2) impacts to national security, and (3) the possible harm to our working relationship with Indian tribes and possible overlap with tribal lands or impacts to tribal usual and accustomed (U&A) areas.

Economic Impacts

The FEA (IEc 2021) prepared by Industrial Economics, Incorporated (IEc), sought to determine the impacts on economic activities due to the designation of the additional critical habitat, above and beyond—or incremental to—those ''baseline'' impacts due to existing required or voluntary conservation efforts being undertaken due to other Federal, State, and local regulations or guidelines (IEc 2021). Incremental impacts may include the direct costs associated with additional effort for section 7 consultations (including consultations that otherwise would have been limited to jeopardy issues, reinitiated consultations, or new consultations occurring specifically because of the designation) as well as the direct costs associated with conservation efforts or project modifications that would not have been required under the jeopardy standard. Incremental impacts may also include indirect impacts resulting from reaction to the potential designation of critical habitat and triggering of additional requirements under State or local laws intended to protect sensitive habitat.

To quantify the economic impact of designation, the FEA (IEc 2021) employed the following steps:

(1) Identify the baseline of economic activity and the statutes and regulations that constrain that activity in the absence of the critical habitat designation in the additional areas;

(2) Identify the types of activities that are likely to be affected by the critical habitat designation;

(3) Project the projects and activities identified in Step 2 over space and time based on the best available information on planned projects, permitting schedules, or average annual levels of activity;

(4) Estimate the costs of administrative effort and, where applicable, conservation efforts or project modifications recommended for the activity to comply with the ESA's critical habitat provisions;

(5) Apply well-accepted discounting methods to calculate the present value cost in each year of the analysis and sum over time to calculate the total

present value and annualized impacts; and

(6) Aggregate the costs at the particular area level. (Impacts are reported at the particular area level; particular areas for the analysis are the same as the six specific areas.)

The first step in the analysis was to identify the baseline level of protection already afforded Southern Resident killer whales in the additional areas being proposed as critical habitat. The baseline for this analysis is the existing state of regulation prior to the revision of critical habitat, including the listing of the species under the ESA (and protections under ESA sections 7, 9, and 10); ESA protections for listed salmon given that salmon are included as part of the prey essential feature of critical habitat for the whales; protections due to other co-occurring ESA listings and critical habitat designations, such as those for the Southern DPS of North American green sturgeon (50 CFR 226.219) and leatherback sea turtles (50 CFR 226.207); and other Federal, state and local laws and guidelines, such as the MMPA, Clean Water Act, and state environmental quality laws (IEc 2021).

In step 2, the NMFS West Coast Region's record of section 7 consultations and NMFS' experience and professional judgment in conducting section 7 consultations were used to identify Federal activities that occur within the areas being considered for Southern Resident killer whale critical habitat and that may affect the critical habitat features. Activities occurring adjacent to or upstream of those areas that may affect the water quality and prey availability essential features within the critical habitat areas were also identified. These activities included salmon fisheries and other fisheries that have incidental bycatch of salmon, salmon hatcheries, offshore aquaculture/mariculture, alternative energy development, oil spills and response, military activities, vessel traffic, dredging and dredge material disposal, oil and gas exploration and production, geologic surveys (including seismic surveys), activities contributing to point-source water pollution, power plant operations, liquefied natural gas terminals, and desalinization plants. The FEA (IEc 2021) assumes that future occurrences of these activities within or affecting critical habitat for the whales will result in consultation. The identification of these activities and the associated threats are further discussed in the Final Biological Report (NMFS 2021a) and the FEA (IEc 2021).

In steps 3 and 4, the incremental administrative costs of including analysis of Southern Resident killer whale coastal critical habitat in future section 7 consultations were estimated. The occurrence of the projects and activities identified in step 2 and the estimated number and type of consultations were projected over space and time using the best available information on planned projects, permitting schedules, or average annual level of activities from NMFS' consultation history for 2006–2016 and other information sources (*e.g.,* USACE permit and project data, and interviews with Federal action agencies). The administrative costs of a given consultation vary depending on the type (*i.e.,* informal, formal, programmatic) and specifics of the project, and it may not be possible to predict the level of effort required for each future consultation. The analysis accordingly employed estimated average incremental administrative costs per consultation, which were based on the expected amount of time spent considering adverse modification as part of future section 7 consultations.

As described in Chapter 2 of the FEA (IEc 2021), there are no particular projects or activities for which NMFS considers it likely that section 7 consultation on coastal critical habitat for the killer whales would result in different conservation efforts than section 7 consultation without coastal critical habitat. This analysis refers to ''conservation efforts'' as a generic term for recommendations NMFS may make to modify projects or activities for the benefit of Southern Resident killer whales and/or their habitat, required actions to minimize impacts, or other efforts that action agencies or other entities may otherwise undertake to avoid adverse effects of projects or activities on Southern Resident killer whales and/or their habitat.

We regularly consult on the types of activities relevant to this analysis to consider the potential for jeopardy to the listed killer whales, their listed prey, and other listed species with overlapping ranges, as well as to consider the potential for adverse modification to the critical habitat of other listed species, and we include conservation efforts accordingly. This includes considerations of critical habitat for other listed species which have similar essential features as Southern Resident killer whale critical habitat. For example, the Southern DPS of North American green sturgeon, for which the essential features within nearshore coastal marine critical habitat include, among others, a migratory corridor within marine habitat and water quality with acceptably low levels of contaminants. We anticipate that it is most likely that these baseline conservation efforts would involve measures that would avoid adverse modification of Southern Resident killer whale critical habitat because they directly or indirectly address impacts to the essential features of the whales' critical habitat (water quality, prey, and passage).

In steps 5 and 6, well-accepted discounting methods were used to calculate the present value cost in each year of the analysis, summed over time to calculate the total present value and annualized impact, and then aggregated at the particular area level. As noted above, for the economic analysis, ''particular areas'' were defined to be equivalent to the six ''specific areas'' occupied by Southern Resident killer whales off the coasts of Washington, Oregon, and California. However, due to the difficulty in determining precise locations of future consultations occurring in Areas 1 and 2 off the coast of Washington (because assignment of the consultation to Area 1 or 2 would require specific information about the activity such as its latitude/longitude or depth), the FEA (IEc 2021) presents economic impacts collectively for these two areas.

Additionally, administrative costs of consultations on upstream activities were not assigned to a particular critical habitat area as there is no information available to inform the connection between the particular locations of upstream activities with the downstream effects on particular critical habitat areas. Accordingly, the incremental economic impacts associated with consultations on upstream activities do not reflect the economic impact of designating any given area, but rather the expanded critical habitat as a whole.

The FEA (IEc 2021) estimates the total present value of the quantified incremental impacts to be approximately $710,000 over the next 10 years, assuming a 7 percent discount rate. Total annualized impacts are estimated to be $80,000. The increase in costs between the DEA (IEc 2019) that accompanied the proposed rule and the FEA (IEc 2021) that supports this final rule reflects updates to the timeframe of the analysis and the dollar year, as opposed to changes in the costs of consultations. The evaluation of costs associated with each particular area is complicated by the fact that many activities and consultations span more than one area, and because costs to Areas 1 and 2 could not be estimated separately. However, annualized impacts from projects occurring in only one area (or two in the case of Areas 1

and 2) ranged from a low of $1,300 for area 6 to $10,000 for Areas 1/2. Over 40 percent of estimated impacts occur upstream (or outside of) of critical habitat areas. The largest share of estimated present value economic impacts are associated with dredging and in-water construction and ''other'' activities (see IEc 2021 for more details).

National Security Impacts

During preparations for the proposed revision to Southern Resident killer whale critical habitat, we provided DOD (Navy, Army, and Air Force) with information regarding the areas under consideration for Southern Resident killer whale critical habitat, and requested they identify any impacts to national security that might arise from the proposed designation of critical habitat. In addition, we considered information regarding potential national security impacts provided by the USCG (Department of Homeland Security) in their response to our 90-day finding on the petition to revise critical habitat.

The Army did not provide a response. The Air Force stated that it had not identified any significant concerns with the proposed revision of Southern Resident killer whale critical habitat to include coastal waters along the U.S. West Coast. The Navy stated that it conducts training and testing activities, collectively referred to as ''military readiness activities,'' within the coastal areas being considered for designation as critical habitat. Specifically, military readiness activities occur in the offshore Pacific Northwest Ocean Surface/Subsurface Operating Area (OPAREA), Warning Area 237 (W–237), and the Olympic A and B Military Operation Areas (MOA), which are all considered at-sea components of the Northwest Training Range Complex (NWTRC), as well as in the QRS, which is a component of the Keyport Range Complex. The Navy refers to all the at-sea areas used for training and testing as the Northwest Training and Testing (NWTT) study area. The Navy believes there would be national security impacts where specific coastal areas 1 and 2 proposed for designation overlap with the QRS. The Navy requested exclusion of the QRS (including its associated surf zone off the coast of Pacific Beach, Washington) from the proposed critical habitat based on national security impacts arising from additional mitigation requirements that have the potential to impact the effectiveness of ongoing and future testing activities (NMFS 2021b). During the pre-publication inter-agency review process for the proposed rule (84 FR 49214, September 19, 2019), the Navy also requested exclusion of a 10-km (6.2-mi) buffer around the QRS. The Navy stated that they used site-specific oceanographic conditions and the best available science establishing fish injury thresholds (Popper *et al.* 2014) to determine that sound and energy levels from the largest explosives that could be used in the QRS may cause injuries to fish (*i.e.,* prey species) out to 10 km beyond the boundary of the QRS. If the QRS alone were excluded (without the buffer), the largest explosives in the QRS may affect the prey feature within proposed critical habitat (in the buffer area). The Navy argued that there would be national security impacts if NMFS required additional mitigation that resulted in the Navy having to halt, reduce in scope, or geographically/seasonally constrain testing activities to prevent adverse effects or adverse modification of critical habitat.

The USCG also provided information on potential impacts to national security and maritime safety. The USCG stated that expanded critical habitat might impair its ability to safely conduct defense readiness and additional missions if the designation results in restrictions to the ability of USCG maritime assets to transit, deploy, train, and/or conduct gunnery exercises within the critical habitat areas. These additional missions include emergency response, search and rescue, law enforcement, conservation activities, and training operations. With respect to gunnery exercises, it noted that USCG Section/Station/Maritime Force Protection Unit boats are limited to going a maximum of 10 to 50 mi (16–80.5 km) offshore depending on vessel type, and requiring them to go over 50 mi would be unsafe and provide unrealistic training/gunnery scenarios to effectively become proficient with meeting mission objectives. In general, USCG Sector/Station assets conduct gunnery exercises with small arms and ammunition, pistols, and up to .50 caliber machine guns. Major afloat cutters conduct exercises with small arms and ammunition, in addition to more sophisticated systems (*i.e.,* 25 millimeter (mm), 57 mm, and 76 mm guns, close-in weapon systems), but rarely conduct exercises in the areas under consideration for critical habitat, with the exception of the NWTRC.

Although we have not conducted a section 7 analysis on a particular proposed action and we are not predetermining any future ESA conclusions now, as a general matter, and based on the information currently available, we consider it unlikely that the USCG's routine operations in support of emergency response, homeland security, law enforcement, and conservation affect the essential features of Southern Resident killer whale critical habitat, and, as such, we do not expect designation of critical habitat will have a national security impact on these activities. Separately, we consider the USCG's concerns regarding potential national security impacts to their defense readiness activities to be generally overlapping with those of the Navy, given the similarities in some of the USCG's activities (*i.e.,* gunnery exercises involving small- and large-caliber projectiles, similar to the Navy's surface-to-surface gunnery exercises) and area of operations (*i.e.,* generally the NWTRC). The USCG does not use these types of explosives in their defense readiness activities, and thus we consider it unlikely that the USCG would have national security concerns beyond those conveyed by the Navy.

As documented in our Final ESA Section 4(b)(2) Report (NMFS 2021b), we assessed several factors to evaluate the potential impacts of designating critical habitat within the QRS and a 10-km buffer around it, such as the size and percentage of the QRS and buffer that would be designated; the importance of the area to the Navy mission and military readiness; the likelihood that Navy activities would destroy or adversely modify critical habitat and that NMFS would require project modification to avoid adverse effects or modification of critical habitat, thus potentially negatively impacting the effectiveness of the Navy's training and testing activities); the level of protection provided to one or more essential features by existing DOD safeguards (*e.g.,* management or protection already in place); and the likelihood that other Federal actions may occur in the site that would no longer be subject to the critical habitat provision if the particular area were excluded from the designation.

Other Relevant Impacts—Impacts to Tribal Sovereignty and Self-Governance

The longstanding and distinctive relationship between the Federal and tribal governments is defined by treaties, statutes, executive orders, judicial decisions, and agreements, which differentiate tribal governments from other entities that interact with, or are affected by, the Federal Government. This relationship has given rise to a special Federal trust responsibility involving the legal responsibilities and obligations of the United States toward Indian tribes and with respect to Indian lands, tribal trust resources, and the exercise of tribal rights. Pursuant to

these authorities, lands have been retained by Indian tribes or have been set aside for tribal use. These lands are managed by Indian tribes in accordance with tribal goals and objectives within the framework of applicable treaties and laws. Executive Order (E.O.) 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests.

There is a broad array of activities on Indian lands that may trigger ESA section 7 consultations. Indian lands are those defined in the Secretarial Order American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the ESA (June 5, 1997), including: (1) Lands held in trust by the United States for the benefit of any Indian tribe; (2) land held in trust by the United States for any Indian tribe or individual subject to restrictions by the United States against alienation; (3) fee lands, either within or outside the reservation boundaries, owned by the tribal government; and (4) fee lands within the reservation boundaries owned by individual Indians.

In developing the proposed rule, we reviewed maps and did not identify any areas under consideration as coastal critical habitat that overlap with Indian lands, because the shoreward extent of the areas under consideration for designation is 20 ft (6.1 m) water depth. Based on this, we preliminarily found that there were no Indian lands subject to consideration for possible exclusion. However, our preliminary assessment indicated that the following federally recognized tribes (83 FR 4235; January 30, 2018) have lands that may be in close proximity to areas under consideration for designation as critical habitat for Southern Resident killer whales, have usual and accustomed (U&A) fishing areas that overlap with critical habitat areas, or may otherwise be affected: Confederated Tribes of the Chehalis Reservation, Hoh Indian Tribe, Makah Indian Tribe, Quileute Tribe, Quinault Indian Nation, and Shoalwater Bay Indian Tribe in Washington; Confederated Tribes of Coos, Lower Umpqua, and Siuslaw Indians, Confederated Tribes of the Siletz Indians, and Coquille Indian Tribe in Oregon; and Cher-Ae Heights Indian Community of the Trinidad Rancheria, Hoopa Valley Tribe, Karuk Tribe, Big Valley Band of Pomo Indians, Tolowa Dee-Ni' Nation, Wiyot Tribe, and Yurok Tribe in California. We also identified the non-federally recognized Wintu Tribe of Northern California as a tribal entity that may be affected by critical habitat designation.

We contacted each of these tribes to solicit comments regarding Indian lands that may overlap and may warrant exclusion from critical habitat for Southern Resident killer whales. We also sought information from these tribes concerning other tribal activities that may be affected in areas other than tribal lands (*e.g.,* tribal fisheries in usual and accustomed coastal marine areas).

We received responses from two tribes in Washington and California. The tribes were primarily concerned with the potential impact of the critical habitat designation on tribal fisheries, particularly within U&A fishing areas located in coastal marine waters. As described in the DEA and FEA (IEc 2019, 2021) while it is possible that the critical habitat designation could result in recommendations for changes in fishery management, we consider this unlikely, given the existing consideration of fisheries' impacts on Southern Resident killer whales and their prey (including ESA-listed salmon) in ESA section 7 consultations in the jeopardy analysis and the implementation of management strategies and actions for the conservation and recovery of these species (IEc 2019, 2021). However, we will continue to coordinate and consult with potentially affected tribes throughout the rulemaking process.

Exclusion of Areas Under Section 4(b)(2) of the ESA

As stated previously, the Secretary may exclude an area from designation if he determines the benefits of exclusion outweigh the benefits of designation based on the best available scientific and commercial data. This discretion is limited, however, in that the Secretary may not exclude an area from designation if exclusion will result in the extinction of the species (ESA section 4(b)(2)).

We decided to exercise the discretion delegated to us by the Secretary to conduct an exclusion analysis and balance the benefits of designation against the benefits of exclusion. Benefits of critical habitat designation are those conservation benefits to the species, while benefits of exclusion result from avoiding the impacts of designation identified above. Below we describe the benefits of designation, then further consider and weigh the benefits of designation and exclusion based on economic and national security impacts. (As discussed above, we preliminarily found that there were no Indian lands subject to consideration for possible exclusion). We have broad discretion as to which factors to consider as benefits of designation and benefits of exclusion, and what weight to assign to each factor—nothing in the ESA, its implementing regulations, or our Policy Regarding Implementation of Section 4(b)(2) of the ESA (''4(b)(2) Policy'') limits this discretion (50 CFR 424.19; 81 FR 7226, February 11, 2016). We also relied on a qualitative cost-benefit analysis, as described in Office of Management and Budget (OMB) Circular A–4.

Benefits of Designation

The primary benefit of designation is the protection afforded under section 7 of the ESA, requiring all Federal agencies to ensure their actions are not likely to destroy or adversely modify designated critical habitat. This is in addition to the requirement that all Federal agencies ensure their actions are not likely to jeopardize the continued existence of the species. The revision to the critical habitat designation is also expected to provide benefits by informing the entities engaged in section 7 consultations and the general public about the status of Southern Resident killer whales, including the coastal areas and features (or habitat) important to whales' conservation.

Other forms of benefits that may be attributed to the conservation and recovery of Southern Resident killer whales (although not specifically attributed to the designation of critical habitat), include use benefits (*e.g.,* for wildlife viewing), non-use or passive use benefits (*e.g.,* existence, option, and bequest values), and ancillary ecosystem service benefits (*e.g.,* water quality improvements and enhanced habitat conditions for other marine and coastal species). Some species, including Southern Resident killer whales, also have significant spiritual and cultural value to particular communities, such as tribes. Such values are generally not expressed in monetary terms.

These benefits are not directly comparable to the costs of designation for purposes of conducting the section 4(b)(2) analysis. Ideally, benefits and costs should be compared on equal terms in the same units. However, there is insufficient information regarding the extent of the benefits and the associated values to monetize all of these benefits. Because we could not quantify or monetize all of the benefits of revising the critical habitat designation for Southern Resident killer whale discussed above, we qualitatively described the conservation value of the areas to the DPS.

As discussed in Appendix B of the Final ESA Section 4(b)(2) Report (NMFS 2021b), we considered categories of information to characterize Southern

Resident killer whales' relative use of the particular areas and the importance of physical and biological features in the areas. However, gaps in or limitations of existing data made an evaluation across all of the areas using any sort of quantitative scoring system challenging. For example, the proportion of prey samples collected from each area might be used to characterize the areas' relative importance for foraging, where a higher proportion of samples might indicate greater foraging or prey resources. However, nearly all (93 percent) of the prey samples were collected during field efforts directed by the locations of satellite-tagged whales, and satellite-tagged whales did not go into Area 6, so this metric would underestimate the conservation value of Area 6. (Predation has been observed but not sampled in Area 6; Black *et al.* 2001). Any spatial bias in NMFS' and partners' ability to conduct on-water response in particular locations to collect prey samples would also limit the usefulness of this factor for comparing relative importance of the critical habitat areas. Another potential metric we considered was the proportion of confirmed opportunistic sightings of Southern Resident killer whales observed in the area, or number of sightings per unit area. However, while opportunistic sightings data provide information on when and where whales occur along the coast, they are less useful for informing a relative ranking of the whales' use of the specific areas due to their spatial bias (*e.g.,* sightings may be influenced by locations of population centers or whale watching operations). Therefore, we determined that the most appropriate approach was to qualitatively assess the conservation value of each area using the available data, mindful of the spatial and temporal gaps and potential biases.

Based on the available information on the whales' use of the areas (and considering gaps in information), and the physical and biological features essential to the whales' conservation, we considered the conservation value of each coastal area to be high. However, we considered the value of Areas 1 and 2 to be very high relative to the other coastal areas, given the whales' particularly high use of portions of the areas, as indicated by models of satellite tag data (they are the only coastal critical habitat areas with usage in some locations that is more than two and three standard deviations above the mean), acoustic data indicating higher rates of detections than would be expected based on monitoring effort (Hanson *et al.* 2013), the documented use by all three pods, year-round use of the areas, and observations of foraging with a substantial number of prey samples collected in portions of the areas.

Weighing Economic Impacts

The FEA (IEc 2021) concluded that costs attributed to the revision of the Southern Resident killer whale critical habitat designation are largely administrative in nature and that a majority of those costs are borne by Federal agencies. Only a small cost of consultation (total annualized impacts of $9,000, discounted at 7 percent) are estimated to be borne by a small number (1–8) of non-Federal small entities (businesses or governments).

In accordance with section 4(b)(2) of the ESA, its implementing regulations (50 CFR 424.19) and the 4(b)(2) Policy (81 FR 7226; February 11, 2016), in evaluating the exclusion of areas based on probable economic impacts, we considered the nature of those impacts and not a particular threshold level. Additionally, we considered the following factors:

(1) Section 2 of the ESA provides that a purpose of the act is to provide a means whereby the ecosystems upon which endangered species and threatened species depend may be conserved.

(2) In listing Southern Resident killer whales under the ESA, we concluded that the current and threatened destruction or adverse modification of the species' habitat is likely contributing to fluctuations in abundance and exacerbating the risk of extinction naturally faced by a small population (70 FR 69903, November 18, 2005). We identified contaminants, vessel traffic, and changes in prey availability as factors that have modified the whales' habitat and considered them to be threats to the species.

(3) As described above, the six particular areas under consideration for critical habitat designation are all of high or very high conservation value.

(4) The economic impacts to Federal agencies and non-Federal entities of designating each of the six particular areas are small (the largest annualized impacts are $10,000 in Areas 1 and 2 combined), as is the annualized economic impact of designating the entire area ($80,000). The potential economic impacts borne by non-Federal entities of designating all six areas are even smaller (total annualized impacts of $9,000 over the next 10 years, discounted at 7 percent), with one to eight non-Federal entities expected to be affected. This reflects approximately six consultations per year that may involve non-Federal entities, for example, businesses engaged coastal and in-water construction activities, renewable energy developments, or seismic surveys.

For these reasons, we conclude that the economic benefit of excluding any of the particular areas does not outweigh the conservation benefit of designation. Therefore, none of the areas are excluded based on economic impacts.

Weighing Impacts to National Security and Exclusion

As described above, we consulted with the DOD regarding the activities taking place at sites managed by DOD and the potential impact of designating critical habitat at these sites. A reply from the Air Force (AF) stated: ''At this time the AF has not identified any significant concerns with the proposed addition of Southern Resident killer whale critical habitat to coastal waters along the U.S. West Coast as depicted on the provided map.'' The Navy stated that it believes there would be national security impacts where critical habitat coastal areas 1 and 2 overlap the QRS, including its associated surf zone off the coast of Pacific Beach, Washington, and a 10-km buffer around it, and requested exclusion of this particular area from critical habitat. The Navy provided information on testing activities proposed in the QRS beyond 2020 and into the foreseeable future, and identified national security concerns regarding potential impacts to their national mission and ongoing and future Navy testing activities if critical habitat were designated there or within a 10-km buffer around the QRS.

We weighed the conservation benefits of designation to Southern Resident killer whales against the benefits of exclusion for the combined area of the QRS and a 10-km buffer around it. We considered various factors relevant to assessing the benefits of exclusion including:

(1) The size of the DOD site, the percentage of the DOD site that would be designated (because only a portion of the DOD site is within critical habitat), and the percentage of the proposed specific area(s) that overlaps with the DOD site (because the DOD site overlaps with only a portion of the critical habitat area(s));

(2) The importance of the area to the Navy's national mission (*e.g.,* frequency/intensity of use, complexity of Navy actions within it, and significance and uniqueness of the site to the overall Navy mission);

(3) The likelihood of an ESA section 7 consultation with the DOD in this site;

(4) The likelihood that DOD activities would destroy or adversely modify critical habitat; based on the DOD's activities at the site, and that NMFS would require project modifications to reduce or avoid these impacts;

(5) The level of protection provided to one or more essential feature by existing DOD safeguards (*e.g.,* management or protection already in place); and

(6) The likelihood that other Federal actions may occur in the site that would no longer be subject to the critical habitat provision if the particular area were excluded from the designation.

Depending on available information, each of these factors may weigh either in favor of exclusion of the area or in favor of designation of the area. We give great weight to the national security and defense missions (81 FR 7226; February 11, 2016). We weighed this information against the benefits of designating the site, which was based on the conservation value rating for the specific area(s) overlapping the DOD site, as well as more specific information regarding Southern Resident killer whale use of the DOD site. As documented in the Draft ESA Section 4(b)(2) Report (NMFS 2019b), based on the great weight afforded military impacts, the unique training in support of military readiness that occurs within the QRS, and the potential delay in critical missions in order to complete adverse modification analyses, in the proposed rule (84 FR 49214, September 19, 2019) we found that the national security impacts tip the scale and outweigh the limited impact to conservation values in just over one-fourth of the identified critical habitat Areas 1 and 2 where those areas overlap with the QRS and a 10-km buffer around it. We determined that the benefit to national security of excluding this particular area outweighed the conservation benefit of designation, and exclusion of the area would not result in extinction of the species (DPS). Therefore, we proposed excluding the QRS and a 10-km buffer around it from the critical habitat designation. The total area proposed for exclusion was 1,687.9 mi^2 (4,371.5 km^2) or 9.7 percent of potential coastal critical habitat.

As described above, we received many public comments on the proposed rule (84 FR 49214, September 19, 2019) opposing the exclusion because it would allow the Navy to conduct activities such as sonar and testing of explosives in the excluded area without considering effects to critical habitat. Comments also noted that part of the QRS overlaps with the OCNMS.

As discussed in the Final ESA Section 4(b)(2) Report (NMFS 2021b), to weigh the national security impacts against conservation benefits of a potential critical habitat designation, we considered the size of the requested exclusion and the amount of overlap with the specific critical habitat area; the relative conservation value of the specific area for the Southern Resident killer whale; the importance of the site to the Navy mission and military readiness; the likelihood that the Navy's activities would destroy or adversely modify critical habitat, and the likelihood that NMFS would require project modifications to reduce or avoid these impacts; and, the likelihood that other Federal actions may occur in the site that would no longer be subject to the critical habitat provision if the particular area were excluded from the designation. In response to the public comments, we reconsidered these factors, information provided by the Navy, and requested additional information from the Navy regarding its activities in the portion of the QRS that also falls within the OCNMS.

The QRS and proposed 10-km buffer comprise about 39 percent of Area 1 (Coastal Washington/Northern Oregon Inshore) and about 25 percent of Area 2 (Coastal Washington/Northern Oregon Offshore), and about 28 percent of Areas 1 and 2 combined, but a very small portion of the total critical habitat designations for the Southern Resident killer whale (8.5 percent). The QRS and associated buffer also have a significant degree of overlap with the OCNMS, where certain activities are prohibited or not authorized, including oil, gas, or mineral exploration, development, or production; discharging or depositing any material or other matter; drilling into, dredging, or otherwise altering the seabed, with some exceptions (15 CFR 922.152). Because of these prohibitions, the likelihood of other Federal activities being proposed in this area of the QRS may be limited.

In support of its request for exclusion of this particular area, the Navy pointed to the extensive range of planned activities, which are described in its Final Northwest Training and Testing (NWTT) Supplemental Environmental Impact Statement (SEIS) published on September 18, 2020, and stated that any additional, future modifications to these activities to minimize impacts on Southern Resident killer whale critical habitat would impact the Navy's ability to meet mission requirements. The Navy pointed to the use of explosives, in particular, as being likely to have adverse effects on killer whale prey, although not likely at the population level for salmon prey. In its initial request, dated December 5, 2018, the Navy stated that if additional mitigation requirements result in having to halt, reduce in scope, or geographically or seasonally constrain testing activities to prevent adverse effects to critical habitat, this would in turn impact their ability to test and field new systems and platforms. To avoid potential, additional, spatial restrictions on their activities within the QRS, the Navy also requested exclusion of an additional 10-km buffer around the QRS from the critical habitat designation. The Navy determined the size for this buffer using sound attenuation modeling to calculate the farthest distance at which fish would be expected to be injured from the largest explosive the Navy can reasonably foresee testing in the QRS; and, in subsequent communications, the Navy further clarified that the size of the buffer also incorporated uncertainty for updates in resource-related science, changes in oceanographic conditions that could reduce attenuation, and the evolution of military technologies that may behave differently in the environment. This buffer was then added to the QRS boundaries that overlapped with the Southern Resident killer whale critical habitat.

We continue to find that the Navy has provided a reasonably specific justification to support the requested exclusion of the QRS, and consistent with our Section 4(b)(2) Policy (81 FR 7226, February 11, 2016), we gave great weight to these concerns when analyzing the benefits of exclusion. Our consideration of the multiple factors discussed, coupled with the potential delay in critical missions in order to complete adverse modification analyses, caused us to continue to find that the benefits of excluding the QRS due to national security impacts outweigh the benefits of designating this portion of Areas 1 and 2 as critical habitat for the Southern Resident killer whales. However, we are modifying our proposed exclusion of the buffer area. Specifically, we are not excluding a portion of the 10 km buffer area around the northeast corner of the QRS, extending along the East side of the QRS, where it overlaps with the OCNMS. As detailed in the Section 4(b)(2) Report (NMFS 2021b), we concluded the benefits of designating critical habitat for the Southern Resident killer whales within this portion of the buffer are not outweighed by national security impacts of including that portion at this time.

The Navy does not currently use or currently plan to use explosives in the northeast corner of the QRS extending along the East side of the QRS, where it overlaps with the OCNMS; therefore,

potential impacts to the Southern Resident killer whale critical habitat are unlikely to extend into the OCNMS. The Navy provided additional information to NMFS clarifying the impact to national security should the full 10 km buffer around the QRS not be excluded from designation as critical habitat. The Navy noted that the current limitation on conducting underwater explosives in this portion of the QRS is based on mitigation measures the Navy proposed in its NWTT SEIS (September 2020) and associated ESA and MMPA compliance documentation, which preclude the use of all underwater explosives for training and testing within 50 nmi from shore, with the exception of mine countermeasures neutralization activities which occur in the QRS where it does not overlap with the OCNMS. The Navy concluded it was practicable to implement this restriction; however, all Navy mitigation measures allow for deviations (in consultation with NMFS) if driven by new and immediate national security requirements. Further, the Navy reviews its mitigation measures annually and can modify those mitigation measures as driven by evolving military readiness requirements, also in consultation with NMFS. The Navy stated that because techniques and tactics needed for national security can rapidly evolve, it is possible that modifications to current activities and the development of new technologies will require testing in areas that may not be currently utilized for underwater explosives.

Furthermore, the portion of the buffer that extends beyond 10 km into the OCNMS, which we are not excluding, comprises an area of very high conservation value to the whales. As described in the Final ESA section 4(b)(2) Report, we considered the conservation value of Areas 1 and 2 to be very high relative to the other coastal areas, given the whales' high use of portions of the areas particularly for foraging, the documented use by all three pods, and year-round use of the areas (NMFS 2021b). Not excluding this portion of the buffer also creates a corridor of critical habitat between the coastline and the eastern boundary of the QRS for most of the length of the QRS exclusion, which supports whale passage between critical habitat areas to the north and south of the QRS exclusion. Given the very high conservation value of this area for the whales, though there are national security impacts as described by the Navy, we found that the benefits of excluding this portion of the buffer due to national security impacts did not outweigh the conservation benefits of designating this area (*e.g.,* see Appendix A Figure 4, Section 4(b)(2) Report, NMFS 2021b) as critical habitat for the Southern Resident killer whales. NMFS notes that should the Navy's requirements change in such a manner that materially affects how it will conduct activities within the QRS, the Navy will provide NMFS with an updated explanation of impacts to national security and NMFS will reconsider whether those impacts outweigh the benefits of retaining a portion of the 10 km buffer areas as critical habitat.

With this reduction in extent of the 10 km buffer within OCNMS, the total area of exclusion in the final rule is 1,400.4 mi^2 (3,627 km^2) or 8.1 percent of potential coastal critical habitat. This final excluded area comprises 24.4 percent and 22.7 percent of areas 1 and 2 each, respectively, but generally not in portions of areas 1 and 2 that have the highest use by Southern Resident killer whales.

Final Revised Critical Habitat Designation

We are designating approximately 15,910 mi^2 (41,207 km^2) of marine habitat within the area occupied by Southern Resident killer whales along the coasts of Washington, Oregon, and California. Combined with the currently designated critical habitat in inland waters of Washington (2,560 mi^2 (6,630 km^2)), the total designation comprises approximately 18,470 mi^2 (47,837 km^2). In both the currently designated and new critical habitat, areas with water less than 20 ft (6.1 m) deep are not included as critical habitat. As described in the preamble to the final rule designating critical habitat in inland waters (71 FR 69054; November 29, 2006), due to a lack of bathymetry data, we were not able to subtract the shallow areas from the estimate of the inland critical habitat area, so the estimated area of this portion of the critical habitat is an overestimate. However, high-quality shoreline and bathymetry data were available for the outer coastal areas, so we were able to interpolate a 20-ft depth contour as the inshore boundary and include only the designated areas in the coastal area calculations. However, the coastal shoreline product we used to delineate the coastal areas, NOAA's Continually Updated Shoreline Product, uses mean high water as the vertical datum (the surface of zero elevation to which heights are referenced), so the inshore boundary of coastal critical habitat is 20 ft of water depth relative to mean high water and, therefore, our estimates of area are more accurate. This is in contrast to the inshore boundary for critical habitat in inland waters, which uses 20 ft water depth relative to extreme high water, which overestimates total area.

The designated areas are occupied and contain physical or biological features that are essential to the conservation of the species and that may require special management considerations or protection. The Navy's QRS and a modified 10-km buffer around it is not included in the designation (and is not included in the area calculations above) because we determined the benefits to national security of exclusion (that is, avoiding the impact that would result from designation) outweigh the benefits of designation. We determined that the economic benefits of excluding any of the areas do not outweigh the benefits of designation. Therefore, we are not excluding any areas based on economic impacts. Section 4(b)(2) does not allow the agency to exclude areas if exclusion will result in extinction of the species. We are excluding only a small percentage of the whales' habitat (8.1 percent of coastal habitat; 7.0 percent of coastal and inland habitat combined) because of impacts to national security. The exclusion does represent a larger portion of the two specific critical habitat areas off the coast of Washington (around 23–24 percent of each of these two coastal areas), which are considered high-use and important foraging areas for Southern Resident killer whales. But, the highest use areas for foraging are just south of the QRS, and only a small portion of the highest use areas are within the 10-km buffer or the QRS. Given the small percentage of total coastal habitat and that most of the highest use by Southern Resident of Washington areas is not in the QRS, we conclude that the exclusion of these areas will not result in extinction of the Southern Resident killer whale DPS. No unoccupied areas are included in this designation.

Effects of Critical Habitat Designation

Section 7(a)(2) of the ESA requires Federal agencies, including NMFS, to ensure that any action authorized, funded or carried out by the agency (agency action) is not likely to jeopardize the continued existence of any threatened or endangered species or destroy or adversely modify designated critical habitat. When a species is listed or critical habitat is designated, Federal agencies must consult with us on any agency action that may affect the listed species or its critical habitat. During the consultation, we evaluate the agency

action to determine whether the action may adversely affect listed species or critical habitat and issue our findings in a biological opinion. If we conclude in the biological opinion that the agency action would likely result in the destruction or adverse modification of critical habitat, we would also recommend any reasonable and prudent alternatives to the action. Reasonable and prudent alternatives are defined in 50 CFR 402.02 as alternative actions identified during formal consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that would avoid the destruction or adverse modification of critical habitat.

Regulations at 50 CFR 402.16 require Federal agencies that have retained discretionary involvement or control over an action, or where such discretionary involvement or control is authorized by law, to reinitiate consultation on previously reviewed actions in instances where: (1) Critical habitat is subsequently designated; or (2) new information or changes to the action may result in effects to critical habitat not previously considered in the biological opinion. Consequently, some Federal agencies may request reinitiation of consultation with NMFS on actions for which formal consultation has been completed, if those actions may affect designated critical habitat. Activities subject to the ESA section 7 consultation process include activities on Federal lands, as well as activities requiring a permit or other authorization from a Federal agency (*e.g.,* a section 10(a)(1)(B) permit from NMFS), or some other Federal action, including funding (*e.g.,* Federal Highway Administration (FHA) or Federal Emergency Management Agency (FEMA) funding). ESA section 7 consultation would not be required for Federal actions that do not affect listed species or critical habitat, and would not be required for actions on non-Federal and private lands that are not carried out, funded, or authorized by a Federal agency.

Activities That May Be Affected

ESA section 4(b)(8) requires, to the maximum extent practicable, in any regulation to designate critical habitat, an evaluation and brief description of those activities (whether public or private) that may adversely modify such habitat or that may be affected by such designation. A wide variety of activities may affect Southern Resident killer whale critical habitat and may be subject to the ESA section 7 consultation processes when carried out, funded, or authorized by a Federal agency. These include: (1) Salmon fisheries and other fisheries that have incidental bycatch of salmon; (2) salmon hatcheries; (3) offshore aquaculture/mariculture; (4) alternative energy development; (5) oil spills and response; (6) military activities; (7) vessel traffic; (8) dredging and dredge material disposal; (9) oil and gas exploration and production; (10) mineral mining (including sand and gravel mining); (11) geologic surveys (including seismic surveys); and (12) activities occurring adjacent to or upstream of critical habitat that may affect essential features, that we refer to as ''upstream'' activities (including activities contributing to point-source water pollution, power plant operations, liquefied natural gas terminals, desalinization plants). Section 7 consultations must be based on the best scientific and commercial information available when they are undertaken, and outcomes are case-specific. Inclusion (or exclusion) from this list, therefore, does not predetermine the occurrence or outcome of any consultation.

Private or non-Federal entities may also be affected by this critical habitat designation if a Federal permit is required, Federal funding is received, or the entity is involved in or receives benefits from a Federal project. These activities would need to be evaluated with respect to their potential to destroy or adversely modify Southern Resident killer whale critical habitat. For ongoing activities, this designation of critical habitat may trigger reinitiation of past consultations. Although we cannot predetermine the outcome of section 7 consultations, we do not anticipate at this time that the outcome of reinitiated consultations would likely require additional conservation efforts, because effects to Southern Resident killer whales and their prey species would in most instances have been assessed in the original consultation. We are committed to working closely with other Federal agencies to conduct any reinitiated consultations in an efficient and streamlined manner to the maximum extent possible and consistent with our statutory and regulatory requirements. Questions regarding whether specific activities would constitute destruction or adverse modification of critical habitat should be directed to NMFS (see **ADDRESSES** and **FOR FURTHER INFORMATION CONTACT**).

Technical Changes to the Southern Resident Killer Whale Critical Habitat Regulations

In addition to designating coastal critical habitat, we are making three technical changes to the existing Southern Resident killer whale critical habitat regulations in 50 CFR 226.206. First, the introductory paragraph of the existing regulations states that the textual descriptions of critical habitat are the definitive source for determining the critical habitat boundaries and the overview map is provided for general guidance purposes only. In 2012, NMFS and the USFWS revised the ESA implementing regulations to specify that the boundaries of critical habitat as mapped or otherwise described in the regulations will be the official delineation of the designation (77 FR 25611; May 1, 2012). To comply with this revision, we are deleting the second and third sentences of the introductory paragraph of 50 CFR 226.206, and replacing them with the following: The maps, clarified by the textual descriptions in this section, are the definitive source for determining the critical habitat boundaries.

Second, the existing regulations specify primary constituent elements (PCE) essential for conservation of Southern Resident killer whales. In 2016, NMFS and the USFWS revised the ESA implementing regulations to remove the term PCE and replaced it with the statutory term ''physical or biological features'' (81 FR 7226; February 11, 2016). These are also referred to as ''essential features.'' To comply with this revision, we are revising 50 CFR 226.206(c) by replacing the term PCE with the term ''essential features.''

Third, we are moving the map(s) to the end of the section to accommodate the additional text necessary to describe the newly added critical habitat areas.

References Cited

A complete list of all references cited in this final rule can be found on our website at *www.westcoast.fisheries.noaa.gov/protected_species/marine_mammals/killer_whale/critical_habitat.html* or the Federal e-Rulemaking Portal at *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2014-0041,* and is available upon request from the NMFS West Coast Region office in Seattle, Washington (see **ADDRESSES**).

Classification

Executive Order 12630, Takings

Under E.O. 12630, Federal agencies must consider the effects of their actions

on constitutionally protected private property rights and avoid unnecessary takings of property. A taking of property includes actions that result in physical invasion or occupancy of private property, and regulations imposed on private property that substantially affect its value or use. In accordance with E.O. 12630, the final rule does not have significant takings implications. A takings implication assessment is not required. The designation of critical habitat affects only Federal agency actions (*i.e.,* those actions authorized, funded, or carried out by Federal agencies). Therefore, the critical habitat designation does not affect landowner actions that do not require Federal funding or permits. This designation would not increase or decrease the current restrictions on private property concerning take of Southern Resident killer whales, nor do we expect the final critical habitat designation to impose substantial additional burdens on land use or substantially affect property values. Additionally, a final critical habitat designation would not preclude the development of Habitat Conservation Plans and issuance of incidental take permits for non-Federal actions. Owners of areas included within the critical habitat designation would continue to have the opportunity to use their property in ways consistent with the survival of listed Southern Resident killer whales.

Executive Order 12866, Regulatory Planning and Review

The Office of Management and Budget (OMB) has determined that this final rule is significant for purposes of E.O. 12866 review. The FEA (IEc 2021) and Final ESA Section 4(b)(2) Report (NMFS 2021b) have been prepared to support the exclusion process under section 4(b)(2) of the ESA and our consideration of alternatives to this rulemaking as required under E.O. 12866. To review these documents, see the **ADDRESSES** section above.

Executive Order 12988, Civil Justice Reform

In accordance with E.O. 12988, we have determined that this rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the E.O. We are designating critical habitat in accordance with the provisions of the ESA. This rule uses standard property descriptions and identifies the essential features within the designated areas to assist the public in understanding the habitat needs of Southern Resident killer whales.

Executive Order 13132, Federalism

The E.O. on Federalism, Executive Order 13132, requires agencies to take into account any federalism impacts of regulations under development. It includes specific consultation directives for situations in which a regulation may preempt state law or impose substantial direct compliance costs on state and local governments (unless required by statute). Pursuant to E.O. 13132, we determined that this final rule does not have significant federalism effects and that a federalism assessment is not required. In keeping with Department of Commerce policies and consistent with ESA regulations at 50 CFR 424.16(c)(1)(ii), we requested information for this rule from the appropriate state resources agencies in Washington, Oregon, and California. The designation may have some benefit to state and local resource agencies in that the rule more clearly defines the physical and biological features essential to the conservation of the species and the coastal areas in which those features are found. While this designation would not alter where and what non-federally sponsored activities may occur, it may assist local governments in long-range planning (rather than waiting for case-by-case ESA section 7 consultations to occur).

Where state and local governments require approval or authorization from a Federal agency for actions that may affect critical habitat, consultation under section 7(a)(2) would be required. While non-Federal entities that receive Federal funding, assistance, or permits, or that otherwise require approval or authorization from a Federal agency for an action, may be indirectly impacted by the designation of critical habitat, the legally binding duty to avoid destruction or adverse modification of critical habitat rests only on the Federal agency.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

The long-standing and distinctive relationship between the Federal and tribal governments is defined by treaties, statutes, executive orders, judicial decisions, and agreements, which differentiate tribal governments from the other entities that deal with, or are affected by, the Federal Government. This relationship has given rise to a special Federal trust responsibility involving the legal responsibilities and obligations of the United States toward Indian Tribes and with respect to Indian lands, tribal trust resources, and the exercise of tribal rights. Pursuant to these authorities, lands have been retained by Indian Tribes or have been set aside for tribal use. These lands are managed by Indian Tribes in accordance with tribal goals and objectives within the framework of applicable treaties and laws. E.O. 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests.

There is a broad array of activities on Indian lands that may trigger ESA section 7 consultations. In developing this rule to revise Southern Resident killer whale critical habitat, we reviewed maps and did not identify any areas under consideration for critical habitat along the coast that overlap with Indian lands, because the shoreward extent of the areas under consideration for designation is 6.1 m (20 ft) water depth. Based on this, we preliminarily found that there were no Indian lands subject to consideration for possible exclusion. However, as discussed above, our preliminary assessment indicated that some federally-recognized tribes (83 FR 4235; January 30, 2018) have lands that may be in close proximity to areas under consideration for designation as critical habitat for Southern Resident killer whales, have usual and accustomed fishing areas that overlap with critical habitat areas, or may otherwise be affected. These include: Confederated Tribes of the Chehalis Reservation, Hoh Indian Tribe, Makah Indian Tribe, Quileute Tribe, Quinault Indian Nation, and Shoalwater Bay Indian Tribe in Washington; Confederated Tribes of Coos, Lower Umpqua, and Siuslaw Indians, Confederated Tribes of the Siletz Indians, and Coquille Indian Tribe in Oregon; and Cher-Ae Heights Indian Community of the Trinidad Rancheria, Hoopa Valley Tribe, Karuk Tribe, Big Valley Band of Pomo Indians, Tolowa Dee-Ni' Nation, Wiyot Tribe, and Yurok Tribe in California. We also identified the non-federally recognized Wintu Tribe of Northern California as a tribal entity that may be affected by critical habitat designation.

As discussed previously we contacted each of these tribes to solicit comments regarding Indian lands that may overlap and may warrant exclusion from critical habitat for Southern Resident killer whales. We also sought information from these tribes concerning other tribal activities that may be affected in areas other than tribal lands (*e.g.,* tribal fisheries in usual and accustomed coastal marine areas). We will continue to consult with affected tribes regarding

the implementation of this critical habitat designation.

Executive Order 13211, Energy Supply, Distribution, and Use

E.O. 13211 requires agencies to prepare a Statement of Energy Effects when undertaking a ''significant energy action.'' According to Executive Order 13211, ''significant energy action'' means any action by an agency that is expected to lead to the promulgation of a final rule or regulation that is a significant regulatory action under Executive Order 12866 and is likely to have a significant adverse effect on the supply, distribution, or use of energy. We have considered the potential impacts of this action on the supply, distribution, or use of energy and find the revision to the designation of critical habitat will not have impacts that exceed the thresholds identified in OMB's memorandum M–01–27, Guidance for Implementing E.O. 13211 (*See* IEc 2021).

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996, whenever an agency publishes 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 effects of the rule on small entities (*i.e.,* small businesses, small organizations, and small government jurisdictions). We prepared a final regulatory flexibility analysis (FRFA), which is part of the FEA (Chapter 5, IEc 2021). This document is available upon request and online (see **ADDRESSES**). Results of the FRFA are summarized below.

NMFS listed the Southern Resident killer whale Distinct Population Segment as endangered under the ESA on November 18, 2005 (70 FR 69903), and on November 29, 2006, issued a final rule designating critical habitat for the whales in inland waters of Washington (71 FR 69054). NMFS is now expanding the critical habitat designation by adding waters along the Pacific Coast between Cape Flattery, Washington, and Point Sur, California. The objective of the rule is to utilize the best scientific and commercial information available to expand critical habitat for the Southern Resident killer whale to best meet the conservation needs of the species in order to meet recovery goals. Section 4(a)(3)(A)(ii) of the ESA allows NMFS to revise designations to critical habitat as appropriate and is the legal basis for this rule. This final rule will not impose any recordkeeping or reporting requirements on small entities and will not duplicate, overlap, or conflict with any other laws or regulations.

The expansion of critical habitat for the Southern Resident killer whales is expected to have a limited economic impact, on the order of $80,000 annualized over 10 years. The nature of these costs are administrative efforts to consider potential for adverse modification part of future ESA section 7 consultations. Primarily, consultations are between NMFS and Federal action agencies to evaluate the potential for projects and activities to result in adverse modification of critical habitat. Therefore, most incremental impacts are borne by NMFS and other Federal agencies and not by private entities or small governmental jurisdictions. However, some consultations may include third parties (*e.g.,* project proponents or landowners) that may be small entities. These third parties may bear some portion of the administrative consultation costs.

Of the activities for which future consultations are forecast and expected to result in incremental economic impacts due to the expanded critical habitat designation, only a subset involve third parties that may be small entities. Specifically, consultations on renewable energy development, dredging and in-water construction, and seismic surveying may involve small entities, including small businesses or governments. The analysis anticipates approximately six consultations on in-water and coastal construction activities per year, 0.5 consultations on renewable energy development, and 0.1 consultations on seismic surveys. While the activity forecast includes less than one consultation annually on renewable energy development and seismic surveying, the FRFA evaluates the impacts associated with one consultation on each of these activities to reflect a high-end estimate for a single year. Administrative costs of consultations on fisheries, military activities, and hatchery operations are unlikely to involve third parties beyond NMFS and the Federal action agency.

Because consultations on fisheries activities are conducted on fishery management plans, rather than on individual fishing activities or permits, individual fishermen and fishing entities that would be considered small businesses are not parities to those consultations. As such, they would only incur costs if additional conservation efforts resulted from this critical habitat designation. NMFS was not able to envision a scenario in which the expansion of critical habitat for Southern Resident killer whales would result in changes to management of salmon fisheries and potential associated costs to small fishing businesses. This conclusion was due to a number of factors including strong existing baseline protections stemming from the ESA listing and consequent need for recovery of many salmon populations themselves, existing consideration of fishery impacts and prey availability relative to the potential for jeopardy to Southern Resident killer whales even absent critical habitat, as well as NMFS's experience over the past 15 years implementing the inland waters critical habitat for Southern Resident killer whales, which has not resulted in fishery management changes beyond those already considered as a result of ESA consultation on prey effects relative to jeopardy. Costs of this rule associated with fishing activities would be limited to administrative costs for future consultations, which are borne by NMFS as both the consulting and action agency, and do not include third parties.

For the consultations that may involve third parties, it is not known whether the third parties bearing administrative costs are likely to be large or small entities. The analysis conservatively assumes all third parties involved in these consultations are small entities. The number of small entities bearing these incremental administrative costs in a given year is uncertain. To provide information on the range of potential entities affected and the potential costs borne by these entities, the analysis presents two scenarios reflecting the extremes:

(1) Scenario 1 identifies the maximum number of future consultations involving small entities and assumes that each consultation involves one unique small entity. We estimate the maximum number of future consultations, and accordingly number of potentially affected entities, to be eight. This represents the total number of annual consultations that occur across all critical habitat units involved with in-water construction, renewable energy development, and seismic surveying. Scenario 1 accordingly provides a high-end estimate of the number of potentially affected small entities (assuming each consultation involves a unique third party and all third parties are small entities), and a low-end estimate of the potential effect in terms of the economic effects (*i.e.,* percent of annual revenues) for each entity (total third party costs of the consultations are divided across the high-end number of small entities). This

scenario may overstate the number of small entities likely to be affected by the rule and may understate the potential impact per entity. Under Scenario 1, we estimate that eight small entities have the potential to bear an impact of $1,000 to $1,800 per entity.

(2) Scenario 2 assumes all future costs to an industry are borne by a single small entity within that industry. This scenario may understate the number of small entities affected and overstate the per-entity impacts. As such, this scenario arrives at a low-end estimate of potentially affected entities and a high-end estimate of potential economic cost effects. Under this scenario, one small entity in the in-water construction industry would bear costs of $6,000.

Because the analysis assumes a maximum of one consultation on both renewable energy development and seismic surveying in a single year, the cost estimates for these activities are identical under both scenarios ($1,200 for one small entity in the renewable energy development industry and $1,800 for one small entity in the seismic survey industry). However, for in-water construction and dredging, these scenarios reflect a range of potentially affected entities and associated revenue effects. The actual number of small in-water construction entities affected, and the per-entity revenue effects are likely to be somewhere in the middle. In other words, some subset greater than one and less than 6 of the in-water construction small entities may participate in the section 7 consultations and bear the associated impacts.

Under both scenarios, potential costs borne by small entities are expected to be minor. Ultimately, up to eight small entities per year may bear costs associated with participation in consultation regarding the proposed expansion of critical habitat for Southern Resident killer whale. The total annualized administrative costs that may be borne by these small entities (businesses or governments) is $9,000 (discounted at 7 percent).

The RFA, as amended by SBREFA, requires us to consider alternatives to the proposed regulation that will reduce the impacts to small entities. We considered an alternative of not expanding critical habitat for Southern Resident killer whales within their coastal range because it would impose none of the additional economic, national security, or other relevant impacts described in the FEA (IEc 2021) or the Final ESA Section 4(b)(2) Report. Under this alternative, Southern Resident killer whales would continue to receive protections provided under the ESA, the existing critical habitat, as well as other Federal, state, and local laws. We rejected this alternative because we determined that the expanded critical habitat is prudent and determinable, and the ESA requires critical habitat designation in that circumstance. We also considered alternatives in which we designated all six of the identified ''specific areas'' (*i.e.,* no area excluded), or designated some subset of the ''specific areas'' (*i.e.,* some ''particular areas'' within the identified ''specific areas'' would be excluded). As described in our Final ESA Section 4(b)(2) Report, we considered the economic impacts, impacts to national security, and other relevant impacts that would result from designation, and weighed the benefits of designation against the benefits of exclusion. Ultimately, we selected an alternative in which one particular area was excluded from the designation, the Navy's Quinault Range Site off the coast of Washington and a 10-km buffer around a portion of it, because we considered impacts to national security outweighed the benefits of designating critical habitat there.

Coastal Zone Management Act

Under section 307(c)(1)(A) of the Coastal Zone Management Act (CZMA) (16 U.S.C. 1456(c)(1)(A)) and its implementing regulations, each Federal activity within or outside the coastal zone that has reasonably foreseeable effects on any land or water use or natural resource of the coastal zone shall be carried out in a manner which is consistent to the maximum extent practicable with the enforceable policies of approved State coastal management programs. We have determined that this revision of the critical habitat designation for Southern Resident killer whales is consistent to the maximum extent practicable with the enforceable policies of the approved Coastal Zone Management Programs of Washington, Oregon, and California. This determination was submitted to the responsible agencies in the aforementioned states for review. The Washington Department of Ecology and California Coastal Commission responded to confirm consistency with their coastal management programs.

Paperwork Reduction Act

The purpose of the Paperwork Reduction Act is to minimize the paperwork burden for individuals, small businesses, educational and nonprofit institutions, and other persons resulting from the collection of information by or for the Federal Government. This final rule does not contain any new or revised collection of information. This rule would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations.

Unfunded Mandates Reform Act

In accordance with the Unfunded Mandates Reform Act, we make the following findings:

(a) This final rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute or regulation that would impose an enforceable duty upon State, local, tribal governments, or the private sector and includes both ''Federal intergovernmental mandates'' and ''Federal private sector mandates.'' The designation of critical habitat does not impose an enforceable duty on non-Federal government entities or private parties. The only regulatory effect of a critical habitat designation is that Federal agencies must ensure that their actions are not likely to destroy or adversely modify critical habitat under ESA section 7. Non-Federal entities that receive funding, assistance, or permits from Federal agencies or otherwise require approval or authorization from a Federal agency for an action may be indirectly impacted by the designation of critical habitat, but the legally binding duty to avoid destruction or adverse modification of critical habitat rests squarely on the Federal agency. Furthermore, to the extent that non-Federal entities are indirectly impacted because they receive Federal assistance or participate in a voluntary Federal aid program, the Unfunded Mandates Reform Act would not apply. Nor would critical habitat shift the costs of the large entitlement programs listed above to state governments.

(b) Due to the prohibition against take of Southern Resident killer whales both within and outside of the designated areas, we do not anticipate that this rule will significantly or uniquely affect small governments. As such, a Small Government Agency Plan is not required.

Information Quality Act and Peer Review

Pursuant to the Information Quality Act (section 515 of Pub. L. 106–554), this information product has undergone a pre-dissemination review by NMFS. The signed Pre-dissemination Review and Documentation Form is on file with the NMFS West Coast Regional Office in Seattle, Washington (see **FOR FURTHER INFORMATION CONTACT**).

On December 16, 2004, OMB issued its Final Information Quality Bulletin for Peer Review (Bulletin). The Bulletin

was published in the **Federal Register** on January 14, 2005 (70 FR 2664), and went into effect on June 16, 2005. The primary purpose of the Bulletin is to improve the quality and credibility of scientific information disseminated by the Federal Government by requiring peer review of ''influential scientific information'' and ''highly influential scientific information'' prior to public dissemination. Influential scientific information is defined as information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. The Bulletin provides agencies broad discretion in determining the appropriate process and level of peer review. Stricter standards were established for the peer review of ''highly influential scientific assessments,'' defined as information whose dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest. The Draft Biological Report (NMFS 2019a) and DEA (IEc 2019) supporting the proposed rule are considered influential scientific information and subject to peer review. These two reports were distributed to five independent reviewers for review before the publication date of the proposed rule, and peer review comments were incorporated prior to their dissemination in support of the proposed rulemaking. The peer reviewer comments were compiled into peer review reports that are available at the following website: *https://www.cio.noaa.gov/services_programs/prplans/ID402.html.*

Final reports with updates based on comments were reviewed by NOAA NMFS Science Center experts.

On April 24, 2019, OMB issued memorandum M–19–15 to reinforce, clarify, and interpret agency responsibilities under the Information Quality Act. The memorandum directs agencies to update their agency-specific guidelines within 90 days to be consistent with certain parameters. NOAA has not yet issued revised guidance.

National Environmental Policy Act (NEPA)

NMFS has determined that an environmental analysis as provided for under NEPA is not required for critical habitat designations made pursuant to the ESA. See *Douglas County* v. *Babbitt,* 48 F.3d 1495 (9th Cir. 1995), cert. denied, 116 S.Ct. 698 (1996).

List of Subjects in 50 CFR Part 226

Endangered and threatened species.

Dated: July 22, 2021.

Carrie Robinson,

Acting Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 226 is amended as follows:

PART 226—DESIGNATED CRITICAL HABITAT

■ 1. The authority citation of part 226 continues to read as follows:

Authority: 16 U.S.C. 1533.

■ 2. Revise § 226.206 to read as follows:

§ 226.206 Critical habitat for the Southern Resident killer whale (*Orcinus orca*).

Critical habitat is designated for the Southern Resident killer whale as described in this section. The maps, clarified by the textual descriptions in this section, are the definitive source for determining the critical habitat boundaries.

(a) *Critical habitat boundaries.* Critical habitat is designated to include all areas in paragraphs (a)(1) and (2) of this section.

(1) *Inland waters of Washington State.* Critical habitat includes three specific marine areas of Puget Sound, Washington, within the following counties: Clallam, Jefferson, King, Kitsap, Island, Mason, Pierce, San Juan, Skagit, Snohomish, Thurston, and Whatcom. Critical habitat includes all waters relative to a contiguous shoreline delimited by the line at a depth of 20 ft (6.1 m) relative to extreme high water in each of the following areas:

(i) *Summer Core Area.* All U.S. marine waters in Whatcom and San Juan counties; and all marine waters in Skagit County west and north of the Deception Pass Bridge (Highway 20) (48°24′25″ N/122°38′35″ W).

(ii) *Puget Sound Area.* All marine waters in Island County east and south of the Deception Pass Bridge (Highway 20) (48°24′25″ N/122°38′35″ W), and east of a line connecting the Point Wilson Lighthouse (48°8′39″ N/122°45′12″ W) and a point on Whidbey Island located at 48°12′30″ N/122°44′26″ W; all marine waters in Skagit County east of the Deception Pass Bridge (Highway 20) (48°24′25″ N/122°38′35″ W); all marine waters of Jefferson County east of a line connecting the Point Wilson Lighthouse (48°8′39″ N/122°45′12″ W) and a point on Whidbey Island located at latitude 48°12′30″ N/122°44′26″ W, and north of the Hood Canal Bridge (Highway 104) (47°51′36″ N/122°37′23″ W); all marine waters in eastern Kitsap County east of the Hood Canal Bridge (Highway 104) (47°51′36″ N/122°37′23″ W); all marine waters (excluding Hood Canal) in Mason County; and all marine waters in King, Pierce, Snohomish, and Thurston counties.

(iii) *Strait of Juan de Fuca Area.* All U.S. marine waters in Clallam County east of a line connecting Cape Flattery, Washington (48°23′10″ N/124°43′32″ W), Tatoosh Island, Washington (48°23′30″ N/124°44′12″ W), and Bonilla Point, British Columbia (48°35′30″ N/124°43′00″ W); all marine waters in Jefferson and Island counties west of the Deception Pass Bridge (Highway 20) (48°24′25″ N/122°38′35″ W), and west of a line connecting the Point Wilson Lighthouse (48°8′39″ N/122°45′12″ W) and a point on Whidbey Island located at 48°12′30″ N/122°44′26″ W.

(2) *Coastal marine waters along the U.S. West Coast.* Critical habitat includes six specific marine areas along the coasts of Washington, Oregon, and California. Critical habitat includes all waters relative to a contiguous shoreline delimited by the line at a depth of 20 ft (6.1 m) relative to mean high water in each of the following areas:

(i) *Coastal Washington/Northern Oregon Inshore Area.* U.S. marine waters west of a line connecting Cape Flattery, Washington (48°23′10″ N/124°43′32″ W), Tatoosh Island, Washington (48°23″ N/124°44′12″ W), and Bonilla Point, British Columbia (48°35′30″ N/124°43′00″ W), from the U.S. international border with Canada south to Cape Meares, Oregon (45°29′12″ N), between the 6.1-m and 50-m isobath contours. This includes waters off Clallam, Jefferson, Grays Harbor, and Pacific counties in Washington and Clatsop and Tillamook counties in Oregon.

(ii) *Coastal Washington/Northern Oregon Offshore Area.* U.S. marine waters west of a line connecting Cape Flattery, Washington (48°23′10″ N/124°43′32″ W), Tatoosh Island, Washington (48°23′30″ N/124°44′12″ W), and Bonilla Point, British Columbia (48°35′30″ N/124°43′00″ W) south to Cape Meares, Oregon (45°29′12″ N), between the 50-m and 200-m isobath contours. This includes waters off Clallam, Jefferson, Grays Harbor, and Pacific counties in Washington and Clatsop and Tillamook counties in Oregon.

(iii) *Central/Southern Oregon Coast Area.* U.S. marine waters from Cape Meares, Oregon (45°29′12″ N) south to the border between Oregon and California (42°00′00″ N), between the 6.1-m and 200-m isobath contours. This

includes waters off Tillamook, Lincoln, Lane, Douglas, Coos, and Curry counties in Oregon.

(iv) *Northern California Coast Area.* U.S. marine waters from the border between Oregon and California (42°00′00″ N) south to Cape Mendocino, California (40°26′19″ N), between the 6.1-m and 200-m isobath contours. This includes waters off Del Norte and Humboldt counties in California.

(v) *North Central California Coast Area.* U.S. marine waters from Cape Mendocino, California (40°26′19″ N) south to Pigeon Point, California (37°11′00″ N), between the 6.1-m and 200-m isobath contours. This includes waters off Humboldt, Mendocino, Sonoma, Marin, San Francisco, and San Mateo counties in California.

(vi) *Monterey Bay Area.* U.S. marine waters from Pigeon Point, California (37°11′00″ N) south to Point Sur, California (36°18′00″ N), between the 6.1-m and 200-m isobath contours. This includes waters off San Mateo, Santa Cruz, and Monterey counties in California.

(b) *Essential features.* The essential features for the conservation of Southern Resident killer whales are the following:

(1) Water quality to support growth and development;

(2) Prey species of sufficient quantity, quality, and availability to support individual growth, reproduction, and development, as well as overall population growth; and

(3) Passage conditions to allow for migration, resting, and foraging.

(c) *Sites owned or controlled by the Department of Defense.* Critical habitat does not include the following particular areas owned or controlled by the Department of Defense, or designated for its use, in the State of Washington, including shoreline, nearshore areas around structures such as docks and piers, and marine areas where they overlap with the areas described in paragraph (a) of this section:

(1) Naval Undersea Warfare Center, Keyport;

(2) Naval Ordnance Center, Port Hadlock (Indian Island);

(3) Naval Fuel Depot, Manchester;

(4) Naval Air Station, Whidbey Island;

(5) Naval Station, Everett;

(6) Naval Hospital Bremerton;

(7) Fort Lewis (Army);

(8) Pier 23 (Army);

(9) Puget Sound Naval Ship Yard;

(10) Strait of Juan de Fuca naval air-to-surface weapon range, restricted area;

(11) Strait of Juan de Fuca and Whidbey Island naval restricted areas;

(12) Admiralty Inlet naval restricted area;

(13) Port Gardner Naval Base restricted area;

(14) Port Orchard Passage naval restricted area;

(15) Sinclair Inlet naval restricted area;

(16) Carr Inlet naval restricted area;

(17) Port Townsend/Indian Island/Walan Point naval restricted area;

(18) Crescent Harbor Explosive Ordnance Units Training Area; and

(19) Quinault Range (including the surf zone at Pacific Beach) and a 10-km buffer around most of the Quinault Range, not including the portion of this buffer that extends beyond 10 km into the Olympic Coast National Marine Sanctuary (OCNMS).

(d) *Maps of Southern Resident killer whale critical habitat.*

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Figure 1 to Paragraph (d) – Existing and Revised Critical Habitat for Southern Resident Killer Whales - Overview

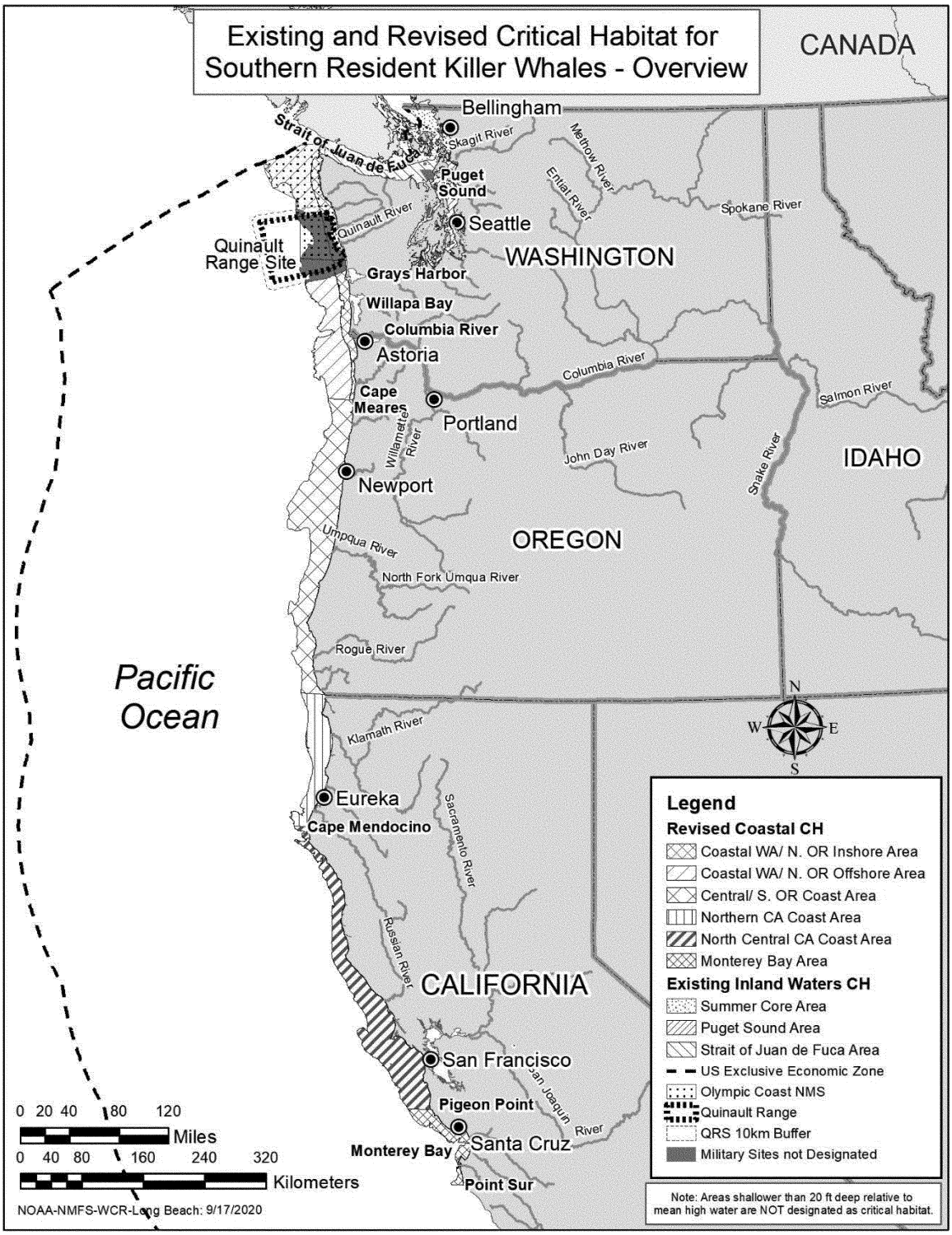
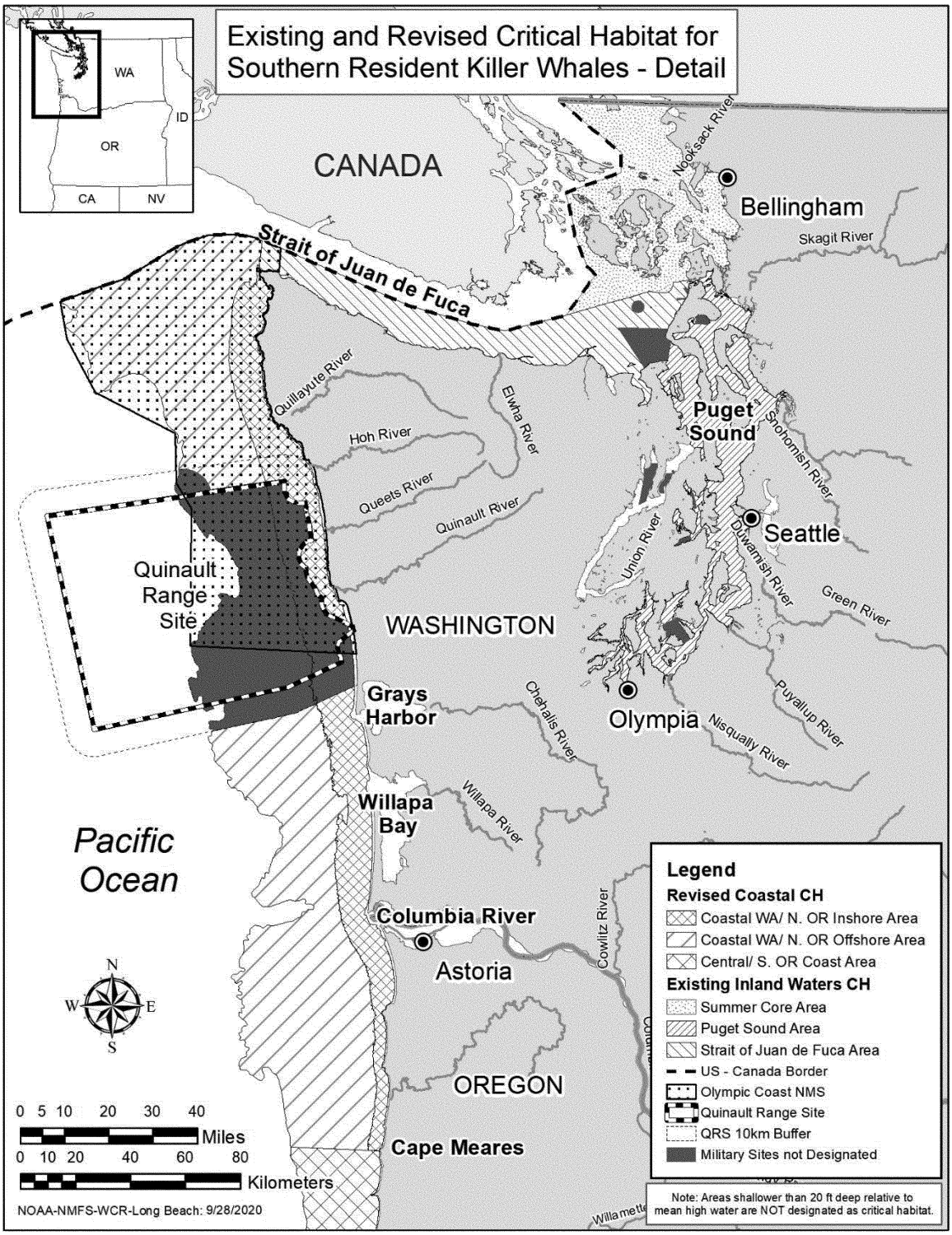


Figure 2 to paragraph (d) – Existing and Revised Critical Habitat for Southern Resident Killer Whales - Detail



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The text of laws is not published in the **Federal Register** but may be ordered in "slip law" (individual pamphlet) form from the Superintendent of Documents, U.S. Government Publishing Office, Washington, DC 20402 (phone, 202–512–1808). The text will also be made available at *https://www.govinfo.gov*. Some laws may not yet be available.

S. 957/P.L. 117–29
To direct the Secretary of Veterans Affairs to ensure that certain medical facilities of the Department of Veterans Affairs have physical locations for the disposal of controlled substances medications. (July 29, 2021; 135 Stat. 306)

S. 1910/P.L. 117–30
Major Medical Facility Authorization Act of 2021 (July 29, 2021; 135 Stat. 307)

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When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

A new table will be published in the first issue of each month.

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